INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 01/01305

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M1/16 B01D61/32 G06F19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 35747 A (AKSYS LTD) 20 August 1998 (1998-08-20)	
A	EP 0 952 540 A (COBE LAB) 27 October 1999 (1999-10-27)	

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Date of the actual completion of the international search	Date of mailing of the international search report
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Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Bichlmayer, K-P

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INTERNATIONAL SEARCH REPORT

[redacted]on on patent family members

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PC[redacted]IB 01/01305

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 9835747	A	20-08-1998	US	5788851 A	04-08-1998
			AU	4056697 A	08-09-1998
			EP	0959980 A1	01-12-1999
			JP	2000504988 T	25-04-2000
			WO	9835747 A1	20-08-1998
			US	6146523 A	14-11-2000
EP 0952540	A	27-10-1999	US	5620608 A	15-04-1997
			EP	0952540 A1	27-10-1999
			EP	0952541 A1	27-10-1999
			CA	2218551 A1	19-12-1996
			DE	69605919 D1	03-02-2000
			DE	69605919 T2	04-05-2000
			EP	0835493 A1	15-04-1998
			ES	2140102 T3	16-02-2000
			JP	11506674 T	15-06-1999
			WO	9641292 A1	19-12-1996

TRAITE DE COOPERATION EN MATIERE DE BREVETS

PCT

RAPPORT DE RECHERCHE INTERNATIONALE

(article 18 et règles 43 et 44 du PCT)

Référence du dossier du déposant ou du mandataire HP 1326	**POUR SUITE A DONNER** voir la notification de transmission du rapport de recherche internationale (formulaire PCT/ISA/220) et, le cas échéant, le point 5 ci-après	
Demande internationale n° PCT/IB 01/01305	Date du dépôt international *(jour/mois/année)* 20/07/2001	(Date de priorité (la plus ancienne) *(jour/mois/année)* 21/07/2000
Déposant GAMBRO DASCO, S.P.A. et al.		

Le présent rapport de recherche internationale, établi par l'administration chargée de la recherche internationale, est transmis au déposant conformément à l'article 18. Une copie en est transmise au Bureau international.

Ce rapport de recherche internationale comprend 3 feuilles.

[X] Il est aussi accompagné d'une copie de chaque document relatif à l'état de la technique qui y est cité.

1. **Base du rapport**

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2. [X] **Il a été estimé que certaines revendications ne pouvaient pas faire l'objet d'une recherche** (voir le cadre I).

3. [ ] **Il y a absence d'unité de l'invention** (voir le cadre II).

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6. La figure **des dessins** à publier avec l'abrégé est la Figure n° 8

   [X] suggérée par le déposant.

   [ ] parce que le déposant n'a pas suggéré de figure.

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   [ ] Aucune des figures n'est à publier.

INTERNATIONAL SEARCH REPORT

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Information on patent family members

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			EP	0952540 A1	27-10-1999
			EP	0952541 A1	27-10-1999
			CA	2218551 A1	19-12-1996
			DE	69605919 D1	03-02-2000
			DE	69605919 T2	04-05-2000
			EP	0835493 A1	15-04-1998
			ES	2140102 T3	16-02-2000
			JP	11506674 T	15-06-1999
			WO	9641292 A1	19-12-1996

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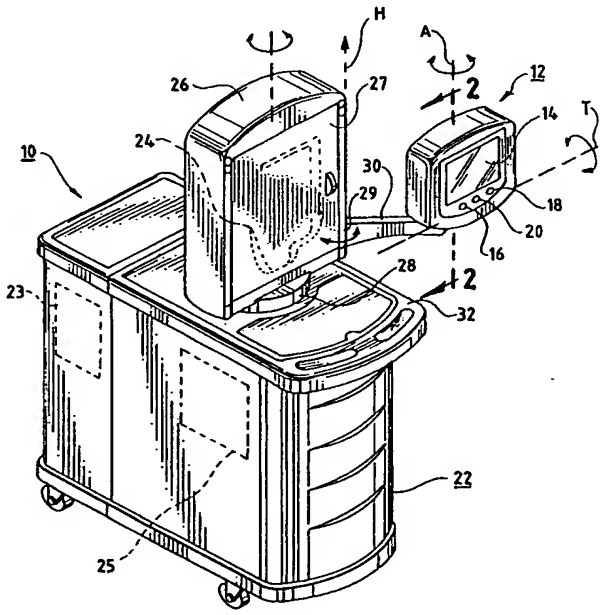
(54) Title: DIALYSIS MACHINES WITH TOUCH SCREEN USER INTERFACE

(57) Abstract

A user interface (12) for a medical instrument such as a dialysis machine (10) is described which uses both a touch screen (14) and hard keys (16, 18 and 20) off of the touch screen (14) to effectuate a change in a parameter associated with the operation of the machine (10). The user interface (12) is connected to extracorporeal circuit (24), mounted above lower cabinet (22) of dialysis machine (10). After the user selects a new parametric value on the touch screen (12), the user presses a hard key (16, 18 or 20) to implement a verification routine to insure that the entered parameter is appropriate for a machine's (10), patient's treatment and the display on the touch screen (14). If the verification procedure ends in a positive result, the user is prompted to press a second hard key (16, 18 or 20) to confirm the change, causing an additional verification check to be performed.



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DIALYSIS MACHINES WITH TOUCH SCREEN USER INTERFACE

NOTICE REGARDING COPYRIGHT

BACKGROUND OF THE INVENTION

A. Field of the Invention

This invention relates to the field of medical instruments and their user interfaces, and more particularly to a user interface and control method for a medical instrument such as a dialysis machine.

B. Description of Related Art

Dialysis machine are used for treating patients with inadequate kidney function. Hemodialysis machines typically include, among other things, an extracorporeal blood circuit comprising an arterial line, a blood pump, a dialyzer having a semipermeable membrane and a venous line. Blood is removed from the patient and pumped by the blood pump through the arterial line to the blood compartment of the dialyzer, where toxins and excess water are removed from the patient's blood. A dialysate solution is circulated on the other side of the membrane and carries away the toxins and removed water. The blood is then returned to the patient via the venous line. Peritoneal dialysis

machines prepare a dialysate solution which is introduced into the patient's peritoneal cavity.

Dialysis machines typically have some sort of controls to regulate the operation of the machine. Such controls in the past were a rather unattractive and hard to use set of dials and switches that required trained medical professionals to use properly. More contemporary machines have a single user interface to allow a patient or medical practitioner to interact with the machine and adjust machine operation or treatment parameters, e.g., blood pump rate, dialysate temperature or flow rate, treatment time, heparin pump rate, etc.

The patent to Grogan et al., U.S. No. 5,326,476, which is incorporated by reference herein, describes a touch screen that is used to control the operation of a hemodialysis machine. The touch screen is connected to a host microprocessor which controls operation of most of the active components of the machine. When the user wishes to change a treatment parameter, the user touches an icon on the touch screen and a key pad with an enter key pops up on the screen. The user enters the new value by touching the numbers on the key pad and pressing the enter button on the key pad. A verify button is then pressed on the touch screen if the user wishes to confirm the change. The patent also briefly describes a method of touching the touch screen to program a time-varying parameter, such as ultrafiltration removal over the course of a dialysis session.

User interfaces that solely depend on a touch screen as a means for entering and confirming parametric values, such as described in the Grogan et al. patent, are vulnerable to failures in the touch screen display. If the touch screen is defective, the computer system may not receive the correct information from the touch screen or

interpret the information incorrectly. The present invention was designed to provide for redundancy and safety verification of parametric value changes independent of the operation of the touch screen, and thereby avoid accidental or unintended changes of parameters in the event of a defect in the touch screen.

The user interface of the present invention provides for the combination of a touch screen, and at least one hard key that are separate and apart from the touch screen, whereby both the touch screen and the hard keys have to be pressed to enter and verify a change in a parametric value pertinent to the treatment or the operation of the machine. The computer control system for the machine also uses host and safety backup microprocessors which are responsive to the touch screen and hard keys to perform internal verification and confirmation checking procedures to verify that the change in parametric value requested by the user is proper. These features combine to offer safety benefits, robustness, and ease of use that are believed to be superior to user interfaces known in the prior art.

Another object of the invention is to provide a user interface design for a medical instrument that is especially easy to use by a person that is not a technically trained medical professional, i.e., by the patient or a member of the patient's family.

SUMMARY OF THE INVENTION

A system for controlling the operation of a dialysis machine is provided comprising in combination a user interface and a central computer control system. The user interface comprises a touch screen that displays messages and information as to the machine status to a user, and permits the user to touch the touch screen to select parametric values pertinent to operation of the machine. The user interface further includes at least one hard key off of the touch screen. The touch screen prompts the user to press the hard key to signify that the selection of the parametric value by the user has been completed.

The central computer control system controls operation of the machine and is responsive to the touch screen and the hard key. The control system comprises a host central processing unit and a safety central processing unit (both comprising microprocessors) operatively connected to each other so as to enable an exchange of information related to the selected parametric value.

When the user presses the hard key to indicate that the selection process is complete, this action causes the host and safety microprocessors to undergo a verification routine whereby the selected parametric value is checked for appropriateness for a patient connected to the machine so as to prevent changes to the parameter potentially harmful to the patient. If the verification routine results in a positive result, the process of changing the parameter may move forward.

In a preferred embodiment, the hard key is directly wired to the safety central processing unit. The user interface also preferably comprises first, second and third hard keys, each of them directly wired to the safety central processing unit. The hard keys

are preferably given a distinctive appearance so as to enable the user to identify each hard key with a distinct functional attribute, e.g., stop, confirm, or entry.

In another aspect of the invention, a method of operation of a dialysis machine is provided, the machine having a central computer control system and a user interface having a touch screen enabling a patient, by touching the touch screen, to select parametric values in a process of changing a parametric value pertinent to operation of the machine or to a dialysis treatment of a patient connected to the machine. The method comprises providing the user interface with at least one hard key and connecting the hard key directly to the central computer control system. After the user has selected the parametric value by touching the touch screen, the user is prompted to press the hard key to either

(a) enter the parametric value selected, or,

(b) if entry of the selected parametric value was accomplished by touching the touch screen, confirm the entry of the parametric value.

In accordance with the above method, a failure in the touch screen to respond to touching of the touch screen to either enter or confirm parametric value changes may be avoided.

In one embodiment of the invention, the central computer control system for the machine preferably includes host and safety CPUs, each comprising a microprocessor. The host and safety microprocessors each have has a first memory such as a random access memory (RAM) and a second memory, such as a hard disk, storing machine operation instructions and treatment prescriptions. In one aspect of the invention, a method is provided for using the touch screen, two hard keys, the first and second memories and host and safety microprocessors to change parameters to provide

enhanced redundancy and safety capabilities and avoid single point failures in the touch screen, host microprocessor, or host memories. The method comprises the steps of:

a) touching the touch screen to select a parametric value;

b) pressing the first hard key to enter the selected parametric value, the computer system responsively storing the selected parametric value in the first memory is associated with the host microprocessor;

c) in response to pressing the first hard key, transmitting data associated with the selected value from the host microprocessor to the safety microprocessor and implementing a verification routine in the safety microprocessor. The safety microprocessor checks the parametric value for appropriateness for a patient connected to the machine so as to prevent changes from being implemented to the parameter potentially harmful to the patent.

d) If the verification routine has a positive result, the safety sends a signal back to the host microprocessor granting approval to the change and stores the changed parameter in its first memory. The touch screen then displays a message prompting the user to press the second hard key to confirm the change selected in step a).

e) If the user presses the second hard key to confirm the change, the host and safety microprocessors stores the new value in their respective second memories. The host and safety microprocessors then conduct a checking procedure to insure that the new value has been correctly stored in their second memories.

These and many other aspects and features of the invention will be more apparent from the following detailed description of preferred embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

In the following detailed description of presently preferred and alternative embodiments of the invention, reference will be made to the accompanying drawing figures, in which like reference numerals refer to like elements in the various views, and in which:

Figure 1 is an illustration of a dialysis machine having a user interface in accordance with a preferred embodiment of the invention.

Figure 2 is a cross-sectional view of the user interface in an embodiment in which the arm connecting the user interface to the machine is attached to the lower cabinet of the machine;

Figure 3 is a block diagram of a control system governing the operation of the machine of Figure 1.

Figure 4 is an elevational view of the user interface for the machine of Figure 1, showing the general organization of the screen into discrete regions associated with different general functions.

Figure 5 is an illustration of the user interface of Figure 4, with the touch screen displaying a dialysis prescription during a treatment session, the display requesting the patient to press an icon associated with a treatment parameter if they wish to change a parameter.

Figure 6 is an illustration of the user interface of Figure 1 after the user has pressed the icon shown in Figure 5, showing up and down arrows that permit the user to select a different value for the treatment parameter.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Figure 1 is an illustration of a dialysis machine 10 having a user interface 12 which may be employed in practicing the invention. The dialysis machine 10 in the preferred embodiment is a machine suitable for use outside of a traditional dialysis clinic setting, such as the home, nursing home or self-care clinic environment. The user interface 12 is designed to be easy to use by a person other than a trained health care professional, such as the patient or a family member of the patient.

The preferred user interface 12 comprises a transparent touch screen 14, a display positioned immediately behind the touch screen 14, and a set of three hard keys or buttons 16, 18, 20 positioned below the touch screen 14. The touch screen 14 and hard keys 16, 18 and 20 are incorporated into a rigid housing 15 that is mounted to the distal end of a moveable arm 30.

The machine 10 has a central computer control system 100 shown in block diagram form in Figure 3. The control system 100 is programmed to display information and messages to the patient or user of the machine on a display 14' (Figure 2) immediately behind the touch screen surface 14. The control system 100, in cooperation with the hard keys 16, 18, 20 and touch screen 14, permits the user to change machine settings and enter information and otherwise control the operation of the machine before, during and after the treatment time.

The dialysis machine 10 of Figure 1 has a water treatment module 23 and a dialysate preparation module 25 contained within the lower compartment 22 of the machine. These modules 23, 25 play no part in the present invention, and are described in detail in U.S. Patent 5,591,344 to Kenley et al. and assigned to Aksys, Ltd., the assignee of the present invention, and in PCT application publication no. WO

96/25214. These references describe a preferred dialysis machine suitable for use in the home environment. The Kenley et al. U.S. Patent No. 5,591,344 and published PCT application no. WO 96/25214 are both fully incorporated by reference herein. Additionally, the manner in which the dialysate solutions are prepared and circulated through the dialysate circuit is not particularly important to this invention and is well known in the art, and may be as described in the above-referenced Kenley et al. patent, or as described in the above-referenced Grogan et al. patent, or otherwise. Additionally, the user interface and method of operation is applicable to other types of medical instruments.

The dialysis machine 10 further includes an extracorporeal circuit 24 mounted above the lower cabinet 22. The extracorporeal circuit is housed behind a door 27 in an enclosure 26 that is mounted to a turntable 28. The turntable 28 is moveably mounted to the top of the lower cabinet 22 such that the turntable 28, enclosure 26 and extracorporeal circuit 24 are capable of rotation as a unit relative to the lower cabinet 22 about a vertical axis. The purpose of this rotation is to allow the extracorporeal circuit within the door 27 to be placed directly opposite a patient sitting next to the machine 10.

The details of the extracorporeal circuit 24 of the machine 10 of Figure 1 are also not particularly germane to the present dialysis machine user interface. Blood is removed from the patient and introduced into an arterial line, and pumped by a blood pump to the blood chamber of a dialyzer. Blood-borne toxins and excess water are removed from the blood through the membrane of the dialyzer, and the blood is returned to the patient via a venous line. To prevent air from being introduced into the blood being returned to the patient, it is conventional in the dialysis art to place an air trap in the venous line. A method of using the user interface 12 to adjust the level in the air

trap is described in a U.S. patent application of Rodney S. Kenley et al., Serial No. _____, which is incorporated by reference herein. Details of the extracorporeal circuit illustrated in Figure 1 can be found in the published PCT application of Kenley et al., publication no. WO 96/25214 and in the Kenley et al. U.S. Patent No. 5,591,344.

The proximal end of the moveable arm 30 may be either attached to the enclosure 26 via a hinge 29 as shown in Figure 1, to the turntable 28, or to the lower cabinet 22 as shown in Figure 2, such as to a corner of the upper surface of the lower cabinet, e.g., corner 32. Preferably, the user interface arm 30 is connected to the rest of the machine 10 via a hinge 29 or other suitable means such that the arm 30 can rotate about the vertical axis so as to position the user interface in a convenient orientation relative to a patient sitting or reclining next to the machine.

The user interface 12 of Figure 1 is shown in cross section in Figure 2, along the lines 2-2 of Figure 1, in an embodiment in which the arm 30 is connected to the upper surface of the machine housing 22 at the corner 32 A hinge 29 connects the proximal end of the arm 30 to the housing 22 and allows the arm 30 to pivot about a vertical axis. A second hinge 49 at the distal portion of the arm 30 allows the user interface 12 to pivot about a vertical axis. A third hinge 47 in the user interface housing 15 allows the user interface 12 to tilt about a horizontal axis, i.e., to tilt down towards the patient if the patient is seated or reclining in bed, or up if the patient is standing.

The extreme lower portion of the user interface housing 15 has a lower handle portion 17 below the hard keys 16, 18, 20. The handle 17 has an extreme lower lip 17A that allows the user to grasp the interface housing 15, and a relatively large surface 17B extending across a substantial portion of the width of the housing that allows the user to push the user interface back, causing the arm 30 to move about the hinge 29, or

rotate about the tilt hinge 47. The addition of a handle feature as described allows the user to interact with a specific portion of the user interface 12 away from the touch screen 14, whereby the user is less likely to push the touch screen 14 to move the touch screen about and accidentally operate the controls of the machine 10. The lower lip 17A and front surface 17B thus enable a user to manually manipulate the user interface housing 15 in a manner to cause rotation of the user interface about the housing axis H of Figures 1 and 3, the arm axis A, and the tilt axis T.

The front of the user interface housing 15 is substantially flat and includes the substantially transparent touch screen 14 per se. The display 14' for the touch screen is placed within the housing immediately behind the touch screen 14. The hard keys 16, 18, 30 are built into the front surface of the housing 15 immediately below the touch screen 14

Figure 3 is a block diagram of a computer control system module 100 installed in the lower cabinet 22 of the machine 10 that governs the operation of the machine. The use of a central computer control module to control active components of a dialysis machine is well known in the art and described in the above-referenced Kenley et al. and Grogan et al. patents. The module 100 controls the operation of the touch screen display 14' to display messages and information concerning the status of the machine and treatment. The module 100 operates the touch screen display 14' to prompt the user to touch the touch screen 14 and the hard keys 16, 18 in the process of changing parameters or inputting information into the computer system 100.

The touch screen 14 interfaces with the patient or other user and is provided for inputting commands or information from the patient into a human interface (HI) board 108 and displaying messages on the display 14' immediately behind the touch screen 14

surface in response to commands from a host Central Processing Unit (CPU) 110 from the HI board 108.

The hard keys 16, 18 and 20 are each a pair of physical, electrically isolated switches. One switch in each of the hard keys 16, 18, and 20 is preferably directly connected, and essentially hard wired, to a backup or safety CPU 116, and the other switch in the hard keys is connected to a host CPU 110. The switch for the emergency stop hard key 20 for the host CPU 110 is preferably directly connected to host CPU 110 from the HI board 108 over a separate conductor, as shown by the dashed line 101.

While FIG. 3 shows the connection between the hard keys 16, 18 and 20 going to the safety CPU 116 via the HI board 108 and conductor 105, the connection between the hard keys and the safety CPU 116 is considered a direct connection since the only function performed by the HI board 108 is debouncing and electrical interfacing the switch signals before they are sent to the Safety CPU 116. The connection is also considered a "direct connection" in the sense the signal path is intentionally designed to not share any circuitry with the Host CPU 110 or the microprocessor on the HI board 108.

The switch for the Red hard key 20 that is directed to the host CPU 110 is directly connected to the host CPU via the HI board 108, which performs debouncing and electrical interfacing, but the circuit does not share any other circuitry on the HI board 108 and the status of the switch is sent to the host CPU over the conductor 101 as described above. The switch for the host CPU 110 for the green and blue hard keys 18 and 16, respectively, are subject to debouncing by the microprocessor on the HI board 108, and the status of the switches is sent over the bus 103.

A set of indicators 104, including lights and audio indicators, a buzzer 121, and a speaker 106, alert the patient to abnormal conditions in the machine 10, and provide

information as to the status of the modes of operation of the machine. The indicators 104 receive input signals from the host or safety CPU via the HI board 108. The buzzer 121 receives input signals from the safety CPU 116. Thus, audio and visual alarm activities are split among the two microprocessors 110, 116 in case one of them fails to work properly.

The host CPU 110 is connected via high speed digital data busses 111 and 113 to a driver board 112 and an analog board 114. The host CPU 110 comprises a microprocessor and implements a software program governing the operation of the machine stored in a hard disk memory 130 or a read only memory (not shown). The hard disk 130 stores other operational information, such as the patient's prescription, data from the passive components, and data input from the patient via the touch screen. An analog board 114 contains analog to digital converters for converting incoming analog signals from the passive sensors in the machine 22 (such as thermistors, pressure sensors and conductivity cells) into digital signals. The driver board 112 receives commands from the CPU 110 and sends the commands to the valves, pumps, heaters, motors, and other active components of the machine (represented by 120) to cause the components to change their status, e.g., commence or cease operation or change rate, as in the case of a pump, or open and close, as in the case of a valve. The signals from the passive components 122 of the system, for example, the conductivity sensors, pressure transducers, thermistors, etc. provide their inputs to the analog boards 114 and 118. The CPU 110 and driver board 112 together act as a controller for the active components.

The analog board 118 provides digital information on a bus 117 to the safety CPU 116. The safety CPU 116 comprises a microprocessor and acts as watchdog of critical system sensors, and provides enable signals to the driver 112 that allow certain

driver commands to issue to the active components 120 (such as signals to the valve and air pump to raise or lower the level in the drip chamber in the extracorporeal circuit). These features are described in more detail below as they relate to the changing of machine parameters. Communications between the safety CPU 116 and host CPU 110 are passed on data bus 107. The safety CPU 116 activates a buzzer or other suitable alarm 121 if certain alarm conditions are present in the machine.

Both the host and safety CPUs 110 and 116 have an associated random access memory 132 and 134, respectively, for use in processing input information from the touch screen 14, for temporary storage of data, and for performing other tasks. In a preferred embodiment, the host CPU 110 and hard disk 130 are based on an off-the-shelf IBM compatible personal computer platform based on an Intel 386 or 486 microprocessor, or the equivalent. A similar microprocessor platform may be used for the safety CPU 116. Of course, other types of microprocessor platforms may be used. The safety CPU 116 also has its own hard disk memory 123. Note that the Safety and Host CPUs 116 and 110 do not share a hard disk, but rather have their own hard disk, for safety and redundancy reasons.

The host CPU 110 preferably has a modem and telephone line interface, a local area network (LAN) gateway card and interface and/or an RS-232 serial port (not shown) for allowing the machine 10 to receive and send messages to remote locations by a suitable communication link. The choice of which type of input/output interface will depend on where the machine 10 is installed (e.g., the home (modem), in a hospital (LAN interface), in a nursing home (modem and/or RS-232 and/or LAN). Potential entities that may wish to access information from the machine include a physician or nurse, the machine manufacturer, a service technician, and a remote monitoring facility such as a central

station monitoring a plurality of machines. Preferably, machine status and treatment information is stored in the hard disk 130 and is accessible to the outside via the modem and host CPU 110 using an interactive program running on the host CPU 110 and at the remote site. The host CPU computing platform 110 also preferably implements a Microsoft ™ graphical user interface operating system, and also Internet access software to allow messages to be sent to and retrieved from the machine 10 via the Internet.

Figure 4 is an elevational view of the user interface 12 of Figure 1 showing a display on the touch screen 14 that is used prior to the start of the treatment. The illustrated display, and preferably all of the displays for the user interface, is organized into discrete zones or portions extending across the width of the display. This organizational scheme assists the user to know where to look on the display for certain functions, icons, and information throughout all of the displays. One portion is preferably devoted to displaying instruction and status information to the user. Another is preferably devoted to displaying primary treatment and machine activities and functions. A third portion is preferably used for secondary machine activities and functions.

An embodiment of this general organizational scheme is shown in Figure 4. The display has an upper portion 60 devoted to secondary activities and functions, and includes an icon 62 for a guide, which allows the user to gain information as to the machine when the icon 62 is pressed, a messages icon 64 indicating whether the patient has received new messages (e.g., via the Internet or public telephone network), and a problem report icon 66. The problem report icon 66 is a means for the machine to notify the patient of problems in a non-treatment mode. The screen display also has a time and day section 68.

The middle portion of the display 70 conveys status information to the patient, such as when the next treatment time is to begin. The portion 70 is given a paper pad type of look to reinforce the role played by this portion of the screen.

The lower portion 72 has a set of icons related to primary treatment and machine functions. These icons, when pressed, lead to additional screens that allow the patient to obtain information or enter data as to basic machine and treatment functions. These icons include an icon indicating treatment information 74, a dialysis schedule icon 76, a prescription icon 78 and a machine set-up icon 80.

When the user wishes to enter information into the machine from any of these menus, the user presses the touch screen 14 to navigate through various screen displays until they arrive at the appropriate screen for the action they wish to take.

As noted above, the user interface of Figure 4 has at least one hard key (a physical button) positioned below the touch screen 14. Three hard keys are preferably provided, each with a distinctive visual appearance to assist the user to identify the hard key with a distinct functional attribute: a blue hard key 16, a green hard key 18 and a red hard key 20. The hard keys 16, 18 and 20 preferably consist of two electrically independent switches, one sending signals to the safety CPU 116 and the other sending signals to the HI board and host CPU 110 as described above.

The blue hard key 16 is connected to the host CPU 110 via the HI board 608, and is hard wired to the safety microprocessor 116. The blue hard key 16 is solely associated with an entry function. The user presses the blue hard key 16 when the user is finished editing a parameter during the process of changing parametric values for the machine. The blue hard key 16 is directly hard wired to the safety CPU 116 due to the

fact that the safety CPU 116 is involved when parametric values are changed, as discussed below.

The green hard key 18 is a means for the user to confirm parametric value changes and some of the mode transitions of the machine 10. The green hard key 18 is connected to the host CPU 110 via the user interface software and hardware (i.e., HI board 108) and is hard wired to the safety CPU 116. The meaning associated with the pressing of the green hard key 18 also depends on the context of the current display and the current state of the machine 10. Due to safety considerations, the safety CPU 116 must have an independent means for determining the user's intention to change parametric values, i.e., independent of the touch screen or the host CPU, hence the green hard key18 is directly connected and essentially hard wired to the safety CPU 116.

The red hard key 20 is a means for the user to issue an "Immediate Stop" command to the machine 10. The host and safety CPUs 110 and 116 respond by disabling a predetermined group of active components of the machine that leaves the machine in a patient-safe mechanically stopped condition. The meaning of the red hard key 20 is always the same regardless of the state of the machine 10. Unlike the blue and green hard keys, the red hard key 20 is directly connected and essentially hard wired to both the host and safety CPUs. Both microprocessors have the ability to disable the same group of active components, and will, redundant with each other, disable the active components.

As noted above, in order to assist the user to become familiar with the functions provided by the hard keys, they are preferably given a different color. Since one of the keys 20 is associated with an emergency stop function it is given a red color. The other keys 16 and 18 have more latitude in their selection of color, and we prefer to use a

green key 18 to be generally identified with a confirmation function. The third key 16 is identified with an entry function, and is blue in the preferred embodiment. To assist further in reinforcing their different functions, they may be given different shapes, e.g., octagon, square and triangle. Other colors and shapes are of course possible.

In accordance with the invention, the touch screen 14 and hard keys 16 and 18 are used in a process to adjust certain parameters pertinent to the operation of the machine or the dialysis treatment. Figure 5 is an illustration of the user interface 12 showing a display on the touch screen 14 that can be accessed before or during the dialysis session. The touch screen 14 displays a message prompting a user to touch an icon 140 if they wish to change the level of the drip chamber in the extracorporeal circuit. When this icon 140 is pressed, an illustration of the blood drip chamber is displayed on the screen and the user indicates the current level in the illustration. The host CPU determines from the indicated level whether the level needs to rise or fall, and by approximately how much, to bring the level back to a predetermined desired level. This process and variations thereto are described in further detail in the above-referenced Kenley et al. patent application filed concurrently, serial no. _____, incorporated by reference herein.

The display of Figure 5 further includes several icons 142, 144, 146, 148, 150 and 152 that display current treatment settings in numerical form. The region 154 below the icons 142, 144, etc. can be used to display other information or to allow the patient to navigate to the previous screen or additional screens, obtain information, or report problems.

The display of Figure 5 requests the patient to press an icon associated with a treatment parameter if they wish to initiate the process of changing the parameter. When

the user presses an icon, for example, the treatment length icon 148, the display is modified to that shown in Figure 6. Up and down arrows appear below the icons 142, 144, 146 et al. adjacent to the selected treatment parameter and the treatment parameter icon 148 is highlighted, e.g., made a brighter or a different color from the other icons. The user presses the up or down buttons 180, 182 to select the new value. The user then signifies that the editing is complete by pressing the blue hard key 16. After verification procedures are performed, the user is then prompted to confirm the change by pressing the green hard key 18.

In the preferred embodiment of the invention, the above process invokes operations with both the host and safety CPUs 110 and 116 to provide redundancy and safety features, which will now be described in detail in conjunction with Figures 3, 5 and 6.

The user touches one of icons 142, 144, 146, 148, 150 and 152 to indicate which parameter they wish to edit. A pair up and down arrows such as shown in Figure 6 then appear. The user presses the up and down icons to select the new parametric value. In response to a prompt, the user indicates that the editing process is complete by pressing the blue hard key 16. An alternative would be to prompt the patient to press the green hard key, but this is a less desirable alternative since association of the green hard key 18 with a confirmation function would be diluted. A further possibility would be to press the activated icon, e.g., icon 144, a second time in response to a prompt. The preferred action of pressing the hard key 16 off the touch screen 14 initiates storage of the changed parametric value into the working RAM 132 for host CPU 110 (Figure 3). A CRC (Cyclical Redundancy Check) value is calculated by the host CPU 110 for the set of parametric values currently displayed on the screen. The CRC check is

calculated by the host CPU 110 only (at this point), and only in response to the pressing of the blue or entry hard key 16.

The following information is then sent from the host CPU 110 to the safety CPU 116 over the bus 107 in response to a pressing of the entry hard key 16: a unique screen identifier associated with the display currently on the touch screen 14, the current values of all the modifiable parameters displayed on the screen, a unique parameter identifier associated with the parameter to be changed, and the calculated CRC value. The data is stored in the Safety CPU 116's RAM 134.

The safety CPU 116 then performs a verification routine to determine that the requested change to the parameter is appropriate for the patient and is consistent with the current status of the machine 10 and current display, and prevent any changes that could be harmful to the patient. Specifically, in a preferred embodiment, the safety CPU 116 verifies that the screen displayed could be displayed given the current state of the machine 10. It also verifies that only one parametric value, of all the modifiable parametric values associated with the current screen, has changed. It also verifies that the parameter identified by the host microprocessor 110 is editable on the specified screen. If further verifies that the parameter that the host has identified as being the changed parameter is the same one identified by the safety CPU 116. This verification is done by the Safety CPU 116 using its own copy of the treatment information stored in its hard disk 123 and comparing this information with the information sent from the host CPU 110 to determine which parameter for the screen has changed. The safety CPU 116 further verifies that the parametric value that changed passes all range, resolution, format and other appropriate validation and safety tests. This is accomplished by comparing the proposed new value with stored values on the hard disk 123 associated

with permissible range of values and other validation criteria for the patient. The values stored on the hard disk 123 may be either modifiable by a doctor's prescription loaded into the hard disk 123 or validation or safety criteria set at the time of machine manufacture. Finally, the safety CPU 116 calculates a CRC on the set of parametric values currently displayed and determines whether the CRC value matches the CRC value calculated by the host CPU 110. It will be appreciated that the above specific verification routine is not the only possible verification routine and can be modified to be more or less stringent for different parameters and states of the machine.

If the safety CPU 116 detects an error in the verification routine it notifies the host CPU 110 and treats the failure in a manner to that of a triggered protective system, such as by displaying an error message or activating one of the indicators 104 and/or the buzzer 121.

If the safety CPU 116 does not detect an error, it sends a signal to the host CPU 110 indicating the tests were passed and notifying the host 110 that the host 110 may continue. The safety CPU 116 transfers back to the host CPU 110 the data stored in RAM 134 that was forwarded from the host 110 (while keeping a copy in RAM 134), and the CRC calculated by the safety CPU. This data is stored in work space in the host CPU's RAM 132.

The host CPU 110 then compares the CRC calculated by the safety CPU 116 to the host's CRC value, compares all the parameter values returned by the safety CPU 116 to the values it originally sent, and treats any mismatch in a manner similar to that of a triggered protective system.

If the comparison is valid, then the host CPU 116 updates the screen display with the parametric values returned by the safety CPU and stored in RAM 132. The host

CPU 110 then causes the touch screen 14 to display a prompt to the user that they must press the green hard key 18 to confirm the pending change to the displayed parametric value. Note that, up until this point, the data associated with the changed parameter is not yet loaded into the hard disk 130 that contains the program, and thus the machine cannot operate in accordance with the selected parametric value. Rather, a confirmation step must still occur, i.e., a pressing of the green hard key 18 off of the touch screen.

When the user presses the green hard key 18 to confirm the change, the host microprocessor calculates a new CRC file and then writes the RAM 132 copy of the parameters and the CRC to the hard disk 130. The safety CPU 116 simultaneously performs the same actions with its copy of the CRC and the parameters stored in RAM 134, writing the RAM copy and CRC value to its hard disk 123. Both host and safety CPUs will then reload their sets of parameter and CRC data into their respective RAM and verify with each other that the new CRC value agrees with each other. The host CPU 110 then removes the "Press the green key to confirm" prompt and enables a screen navigation prompt allowing the user to navigate through other screens. At this point, the user can either navigate off the screen of Figure 6 or select another parameter for editing. The changing of the parametric value is now complete since the parametric value data is loaded into the hard disks of the host and safety CPU.

While the above discussion has assumed that the user only modifies one of the several parameters from the display of Figure 6, the user may choose to modify another parameter on the same screen after the blue hard key 16 has been pressed. The user does not have to press the green hard key for every single parameter change. For example, the user may select a new blood flow rate (using icon 142), then press the blue hard key 16 to signify completing of the editing process, select a new fluid removal rate (using

icon 146), then press the blue hard key 16, then edit the dialysate temperature (using icon 150), and then press the blue hard key 16. After each pressing of the blue hard key 16, the above-described verification routine is performed. If the verification routine results in a positive result for each pressing of the blue hard key, the display will continue to display a "press the Green hard key to confirm" prompt. The user will press the green hard key once to confirm that they intend to change all the parametric values that have been selected.

Since the new updated parametric value(s) are now entered into the hard disk memory 130, the host CPU 110 commands the relevant active components of the machine 10 in accordance with the new parametric value.

This use of the hard keys in the process of changing parametric values is considered to be distinctly different and an improvement from merely touching the touch screen to enter or change values, since the touch screen can be prone to failures. Failures in a touch screen to properly respond to a touching of the surface can arise in a variety of ways, such from mechanical failures due to repeated use over a prolonged period of time, the screen surface material taking on a depression or set in a particular area from repeated use, electro-static shock causing the grid to fail in particular area, high electromagnetic fields causing the contacts to touch, cleaning agents leaking around the periphery of the screen, and so on. By also using hard keys or physical switches directly wired to the host and safety CPU to change values, the microprocessors have an independent means for determining whether the user has entered values or intends to confirm the changes. Further, by virtue of connecting the hard keys to both microprocessors, and using the pairs of redundant host and safety memories to check against each other, a failure in either microprocessor or associated

memories will be detected, allowing for alarms or other protective action to be initiated while maintaining patient safety,

The above-described method of using the touch screen and hard keys to change machine or treatment parameters is also applicable to changing operational modes in the machine. For example, if the machine 10 is in a prepare dialysate solution mode, the display 14 may display a prompt indicating that the user should press the green hard key to indicate that they are ready to enter into a prepare access site mode or a dialyze mode. Another example would be when the user is finishing the dialysis session and indicates to the machine that they are ready to end dialysis and begin a rinseback mode. The user is prompted to press a hard key (e.g., the green hard key) to indicate that they wish to confirm that they are ready to start the next mode of operation. Further, by virtue of the connection of the hard keys to both the host and safety CPUs, a verification routing can be performed by both CPUs to confirm that the machine is in a state where the change is mode is safe for the patient.

For some mode changes, it is presently contemplated that little or no user interaction with the machine is necessary. For example, the transition from a clean and rinse mode to a prepare dialysate solution mode may be made without requiring user involvement. However, the current mode of operation is preferably communicated to the patient, such as by displaying a message telling the user what mode the machine is in (e.g., clean and rinse mode) and an illustration communicating how much time remains until the machine has completed the present mode.

It will be appreciated that various modifications may be made to the methods described herein without departure from the true scope and spirit of the invention. Furthermore, as used in the claims, the term "touch screen" is intended to mean the

combination of the transparent physical surface touched by the user and the display immediately behind the surface touched by the user. The term "hard key", as used in the claims, is not intended to be limited to a button or key having two physical switches directed to host and safety CPUs, but rather, unless otherwise stated, is intended to mean simply a manually manipulable physical switch off of the touch screen such as a button operatively connected to a central computer system for the medical instrument. This true scope and spirit is defined by the appended claims, interpreted in light of the foregoing specification.

WE CLAIM:

1. A system for controlling the operation of a dialysis machine, comprising, in combination:

a) a user interface comprising :

1) a touch screen displaying messages and information as to said machine to a user and permitting said user to touch said touch screen to select at least one parametric value pertinent to operation of said machine or pertinent to a treatment by said machine, and

2) at least one hard key off of said touch screen, said touch screen prompting said user to press said hard key to signify that the selection of said at least one parametric value by said user has been completed;

b) a control system within said machine for controlling operation of said machine and responsive to said touch screen and said at least one hard key, said control system comprising a host microprocessor and a safety microprocessor operatively connected to each other so as to enable an exchange of information related to said at least one selected parametric value,

c) said pressing of said hard key causing said host and safety microprocessors to undergo a verification routine whereby said selected parametric value is checked for appropriateness for a patient connected to said machine so as to prevent changes to said parameter potentially harmful to said patient.

2. The system of claim 1, wherein said hard key is directly wired to said safety microprocessor so as to permit said safety microprocessor to respond to a pressing of said hard key.

3. The system of claim 1, wherein said user interface comprises first, second and third hard keys, said first hard key associated with an emergency stop function for said machine, said second hard key associated with an entry function for entering said selected at least one parametric value, and said third hard key associated with a confirmation function for confirming that the at least one entered parametric value is intended by said user of said machine, said touch screen prompting said user to touch either said second hard key or said third hard key after said user has touched said touch screen to select said at least one parametric value.

4. The system of claim 1, wherein said user interface comprises at least first and second hard keys, said first hard key having a first color and said second of said hard keys having a second color distinctly different from said first color.

5. The system of claim 4, wherein said user interface comprises a third hard key having a third color, wherein said first color comprises red, and said third color comprises green.

6. The system of claim 1, wherein said user interface comprises first, second and third hard keys, each of said first, second and third hard keys hard wired to said safety microprocessor.

7. The system of claim 1, wherein said user presses a second hard key to confirm that said selected at least one parametric value is intended by said user.

8. In a dialysis machine having a user interface and a central computer system to control the operation of said dialysis machine, said user interface having a touch screen enabling a patient, by touching the touch screen, to select parametric values in a process of changing a parametric value pertinent to operation of said machine or pertinent to a dialysis treatment of a patient connected to said machine, the improvement comprising:

providing said user interface with at least one hard key;

connecting said hard key to said central computer system, and

after said user has selected said parametric value by touching the touch screen, prompting said user of said machine to press said hard key to either

(a) enter said parametric value selected by touching said touch screen, or, if entry of said selected parametric value is accomplished by touching the touch screen,

(b) confirm the entry of said parametric value,

so that a failure in said touch screen to respond to touching of the touch screen to either enter or confirm parametric value changes may be avoided.

9. The improvement to a dialysis machine of claim 8, wherein said improvement further comprises:

providing said central computer system with a host microprocessor and a safety microprocessor and connecting said hard key to both said host microprocessor and said safety microprocessor, with said hard key directly wired to said safety microprocessor.

10. The improvement to a dialysis machine of claim 8, wherein said improvement further comprises:

providing said user interface with first, second and third hard keys, said first hard key associated with an emergency stop function for said machine, said second hard key associated with an entry function for entering said selected parametric value, and said third hard key associated with a confirmation function for confirming that the entered parametric value is intended by said user of said machine, said touch screen prompting said user to touch said second hard key after said user has touched said touch screen to select said machine operation parameter.

11. A method of changing a parametric value pertinent to operation of a dialysis machine, said machine having a user interface comprising a touch screen, a first hard key and a second hard key, and a control system responsive to said first and second hard keys comprising a host microprocessor and a safety microprocessor, said host and safety microprocessors each having a first memory and a second memory storing machine operation instructions, the method comprising the steps of:

a) displaying on said touch screen a display permitting a user to touch said touch screen to select a parametric value associated with a parameter pertinent to operation of said machine or pertinent to a dialysis treatment conducted by said machine;

b) pressing said first hard key to enter said selected parametric value, said control system responsively storing said selected parametric value in said first memory associated with said host microprocessor;

c) in response to pressing said hard key, transmitting data associated with said parametric value and said parameter from said host microprocessor to said safety

microprocessor and implementing a verification routine in said safety microprocessor, wherein said parametric value is checked for appropriateness for a patient connected to said machine so as to prevent changes to said parameter potentially harmful to said patient;

d) if said verification routine has a positive result, prompting said user to press said second hard key to confirm the change selected in step a) and responsively pressing said second hard key and storing said data associated with said parametric value in said first memory associated with said safety microprocessor;

e) storing in said second memory associated with said host and safety microprocessors said data associated with said parametric value; and

f) checking, with said host and safety microprocessors, the contents of their respective first and second memories against each other to insure that said data associated with said parametric value has in their respective first and second memories is the same.

12. The method of claim 11, wherein said second memory associated with said host microprocessor comprises a hard disk storing a prescription for a patient using said machine.

13. The method of claim 11, wherein said first and second hard keys are directly connected to said safety microprocessor.

14. The method of claim 11, wherein said verification routine comprises the steps of:

calculating with said host microprocessor a first cyclical redundancy check value associated with said selected parametric value;

transmitting from said host microprocessor to said safety microprocessor, in addition to said parametric value, said first cyclical redundancy check value, a first identifier associated with a screen displayed by said touch screen during said step of selection of said parametric value, and a second identifier associated with said parameter;

calculating with said safety microprocessor a second cyclical redundancy check value associated with said data;

verifying with said safety microprocessor from said first and second identifiers that said touch screen could display said screen given the current state of said machine and that said parameter may be changed on said screen;

verifying with said safety microprocessor that said parametric value associated with said data is within a predetermined range associated with said parameter, and

verifying with said safety microprocessor that said second cyclical redundancy check matches said first cyclical redundancy check; and, in the event that said verification steps result in a positive result,

transmitting an approval signal from said second microprocessor to said first microprocessor indicating that said positive result was achieved.

15. An improved user interface and screen display apparatus for a dialysis machine that promotes ease of use of said user interface by a user operating said machine without immediate supervision by trained professional medical personnel, comprising:

a) a touch screen;

b) a screen display for said touch screen, said screen display arranged in at least two portions extending across said display, said at least two portions comprising:

1) a first portion displaying instruction and status information to a user of said machine; and

2) a second portion adjacent to said first portion on said display and displaying a plurality of icons, each of said icons associated with a specific functional activities associated either with said machine or a treatment session of said machine; and

c) at least one hard key associated with said display, said first portion of said screen display prompting said user to press said at least one hard key in a process of entering or confirming entry of information into said machine.

16. The apparatus of claim 15, wherein at least one of said icons is selected from the group of icons consisting of treatment icon, a schedule icon, a prescription icon, and a setup and care icon.

17. The apparatus of claim 15, wherein said first and second portions are arranged above each other and extend across the width of said display, and wherein said screen display further comprises a third portion adjacent to said first and second portions, and wherein said third portion of said screen display displays a plurality of icons, at least one of said icons associated with a message transmission or receiving function for said dialysis machine.

18. An ergonomically efficient and easy to use human interface for a dialysis machine, said dialysis machine having an enclosure containing hydraulic circuitry for said machine comprising:

an arm having a proximal end connected to said machine and a free distal end portion;

a display assembly connected to said free distal end portion of said arm, said display comprising a touch screen,

wherein said proximal end of said arm is mounted to said machine in a manner permitting said arm to rotate about at least one axis relative to said machine to thereby position said display at the distal portion thereof in a multitude or different positions relative to said machine; and

wherein said display is connected to said free distal end portion of said arm by a hinge means for permitting a user of said machine to rotate said display about at least one axis relative to said arm.

19. The apparatus of claim 18, further comprising a second hinge means connected to said display for permitting said display to be rotated relative to said arm about a horizontal axis.

20. The apparatus of claim 18, wherein said display further comprises at least one hard key mounted adjacent to said touch screen in said display assembly.

21. The apparatus of claim 20, wherein said display assembly further comprises three hard keys mounted adjacent to said touch screen.

22. The apparatus of claim 21, wherein said three hard keys are each a distinctly different color.

23. The apparatus of claim 21, wherein said three hard keys are each a distinctly different color and wherein at least one of said hard keys has a distinctly different shape from the other two hard keys.

24. An ergonomically efficient and easy to use human interface for a medical instrument especially suited for use by a user other than trained professional medical personnel, comprising:

a) a display assembly comprising a housing having a front surface;

b) a touch screen incorporated into said front surface;

c) a plurality of hard keys incorporated into said front surface placed adjacent to said touch screen, said touch screen displaying a message prompting said user to press both said touch screen and at least one of said hard keys during operation of said human interface of said medical instrument to change a parameter pertinent to said instrument or pertinent to a treatment performed by said instrument on said patient;

d) wherein each of said plurality of hard keys presents a substantially different visual appearance to a user so as to readily permit said user to associate each of said plurality of hard keys with a different functional attribute associated with said operation of said human interface.

25. The user interface of claim 24, wherein said plurality of hard keys comprise first, second and third hard keys each having a distinctly different color.

26. The user interface of claim 25, wherein said first hard key has a red color and associated with a emergency stop function , said second hard key having a blue color and associated with an entry function, and said third hard key has a green color and associated with a confirmation function, said first second and third hard keys located adjacent said touch screen on said front surface of said display.

27. The user interface of claim 25, wherein said display assembly is mounted to a free end of an arm connected to said medical instrument, with said display rotatable relative to said arm about at least one axis.

28. The user interface of claim 25, wherein at least one of said hard keys has a distinctly different shape from the other two of said hard keys.

29. The user interface of claim18, further comprising a handle portion below said touch screen comprising a lower lip enabling a user to grasp said user interface housing and a front surface extending across a portion of the width of said housing, said lower lip and said front surface enabling a user to manually manipulate said user interface housing in a manner to cause rotation of said user interface about said at least one axis relative to said machine and said at least one axis relative to said arm

FIG. 1

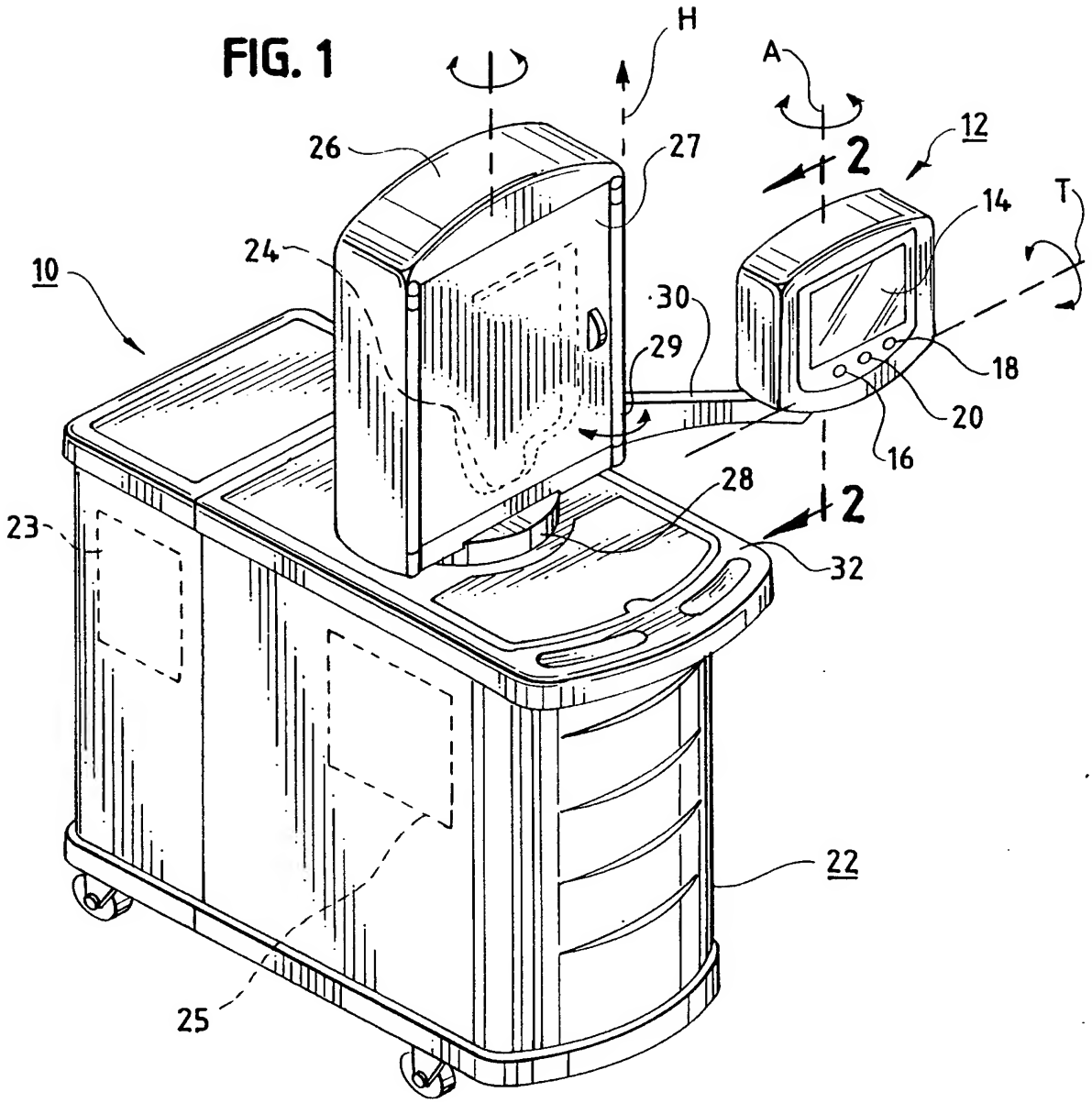


FIG. 2

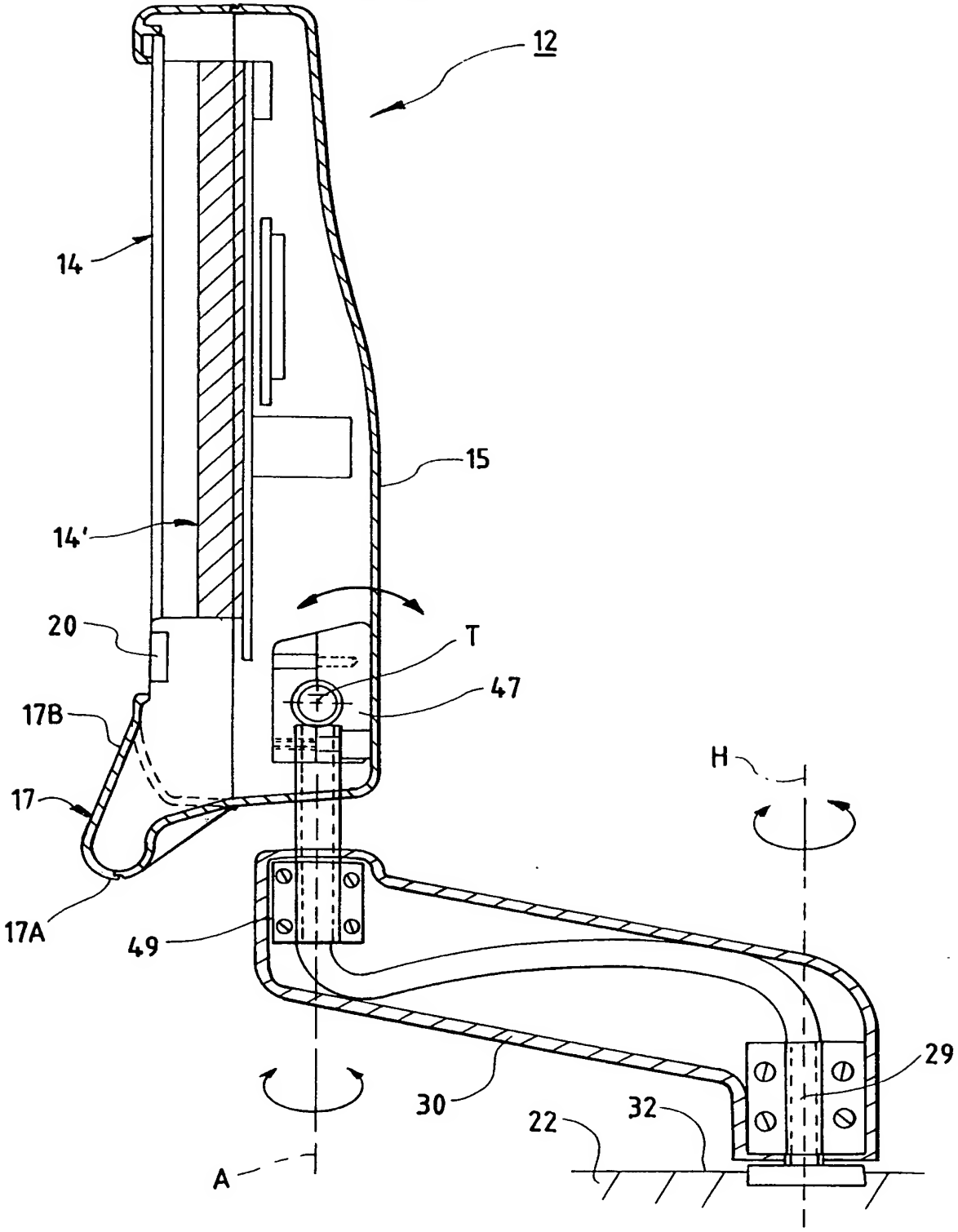


FIG. 3

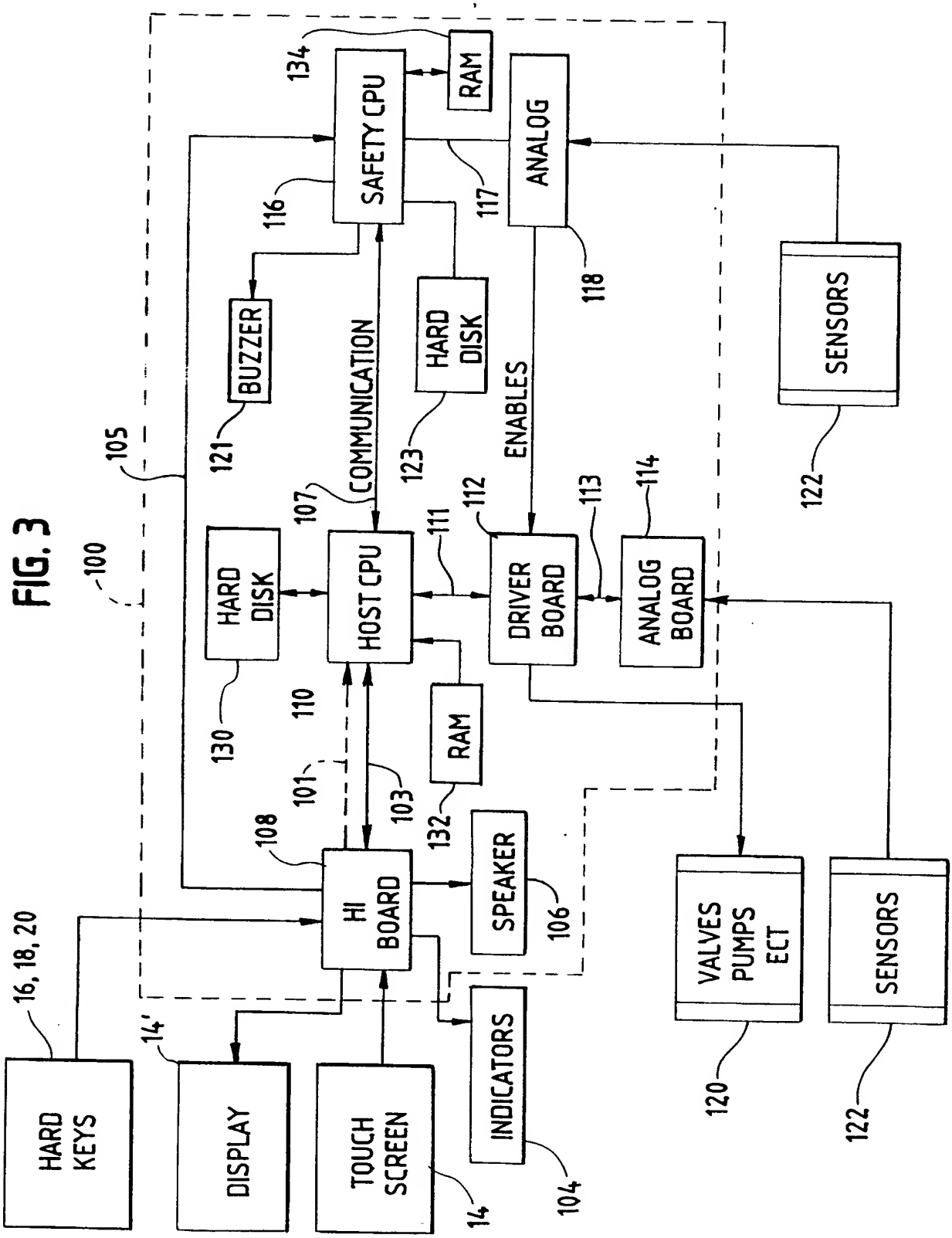


FIG. 4

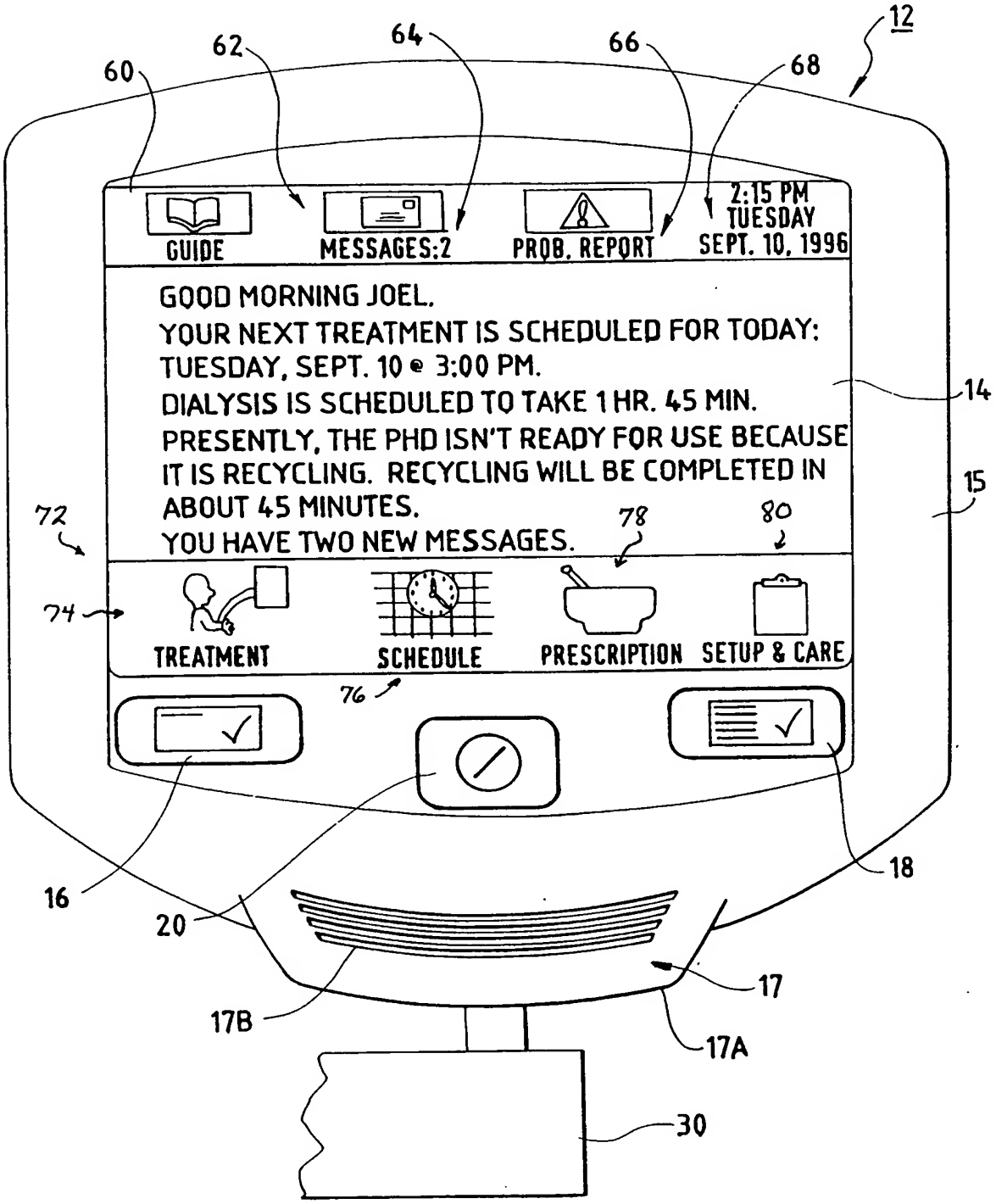


FIG. 5

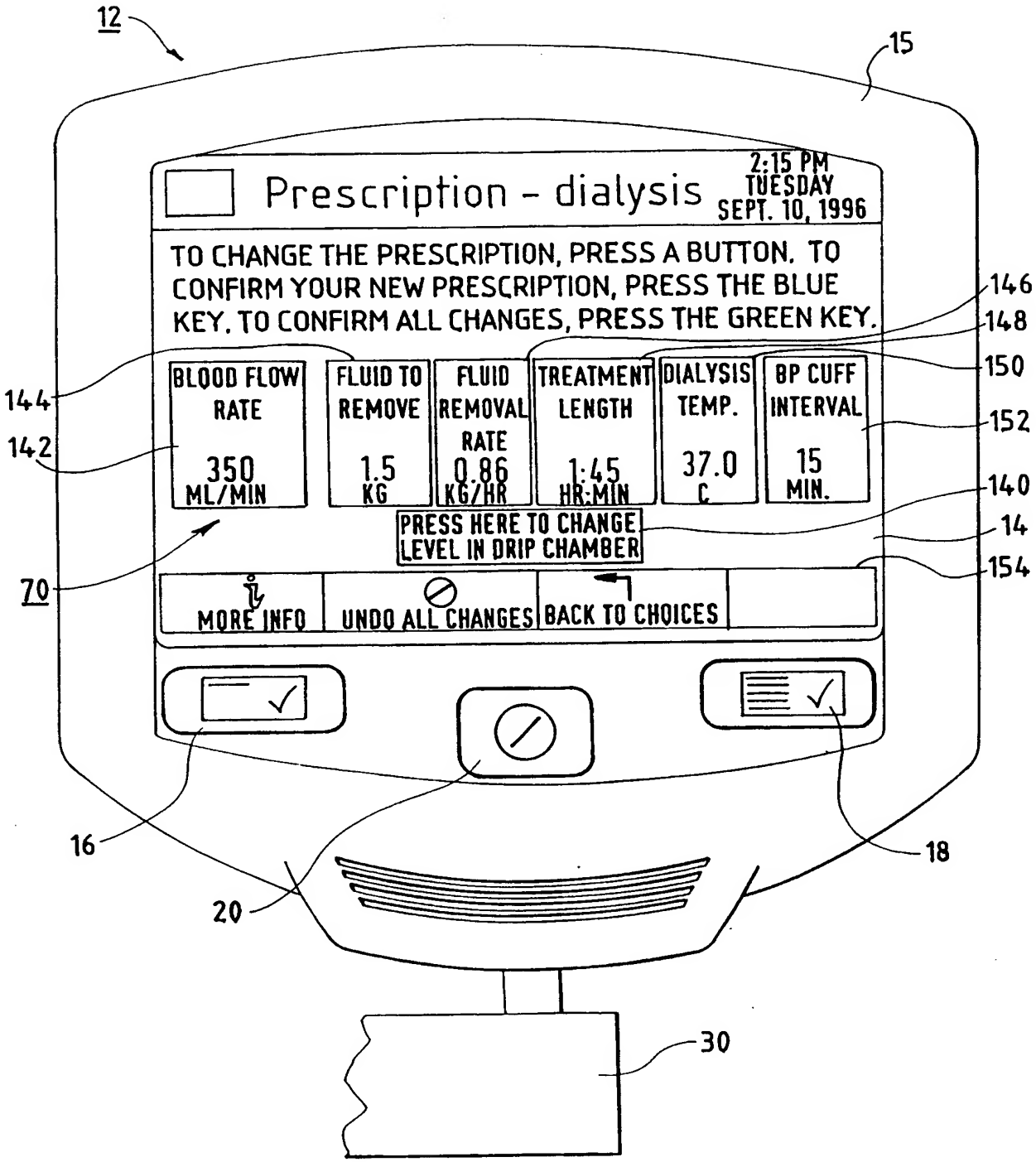
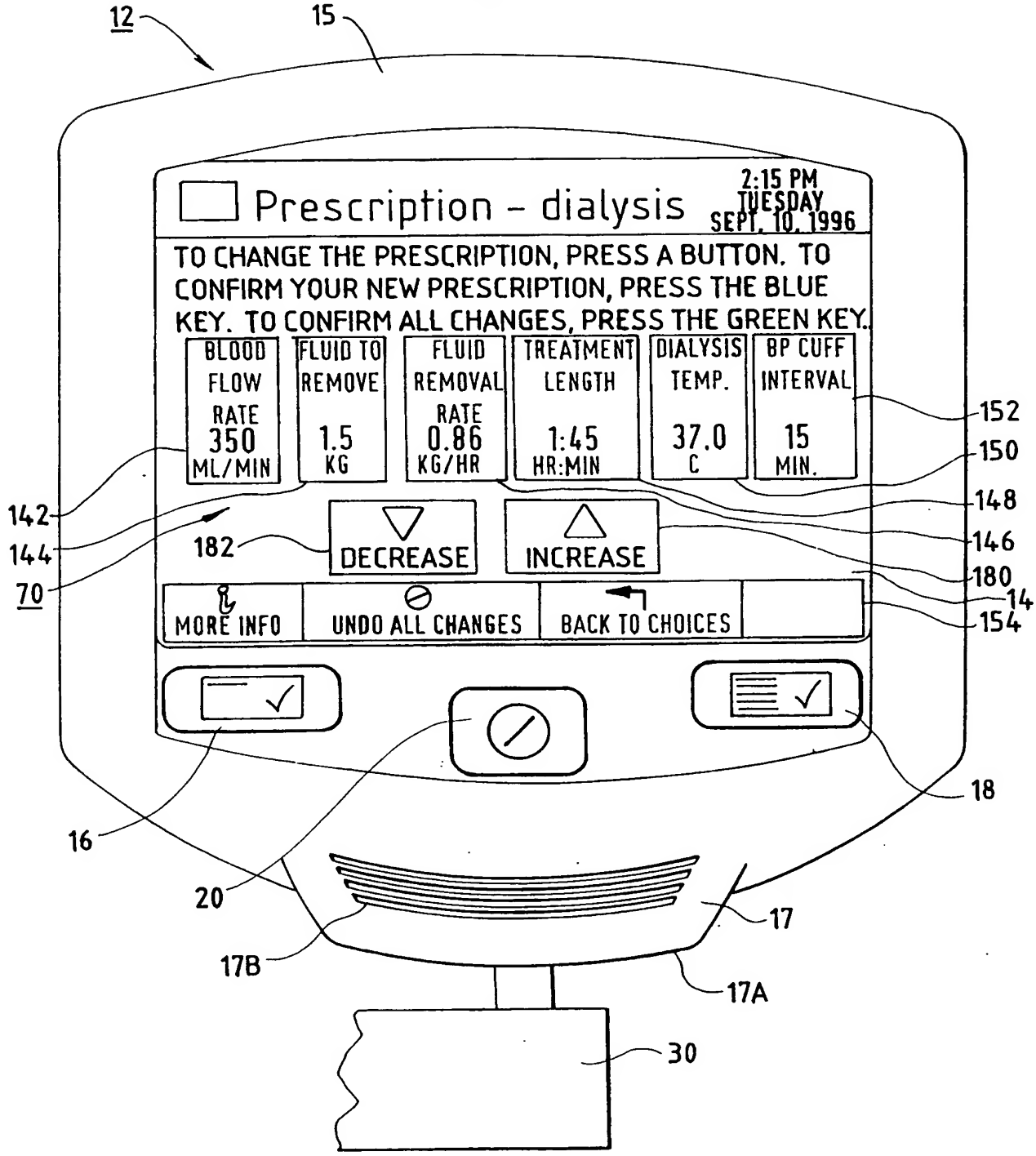

12
15
Prescription - dialysis
2:15 PM
TUESDAY
SEPT. 10, 1996
TO CHANGE THE PRESCRIPTION, PRESS A BUTTON. TO CONFIRM YOUR NEW PRESCRIPTION, PRESS THE BLUE KEY. TO CONFIRM ALL CHANGES, PRESS THE GREEN KEY.
146
148
150
144
142
152
140
14
154
70
BLOOD FLOW RATE
350 ML/MIN
FLUID TO REMOVE
1.5 KG
FLUID REMOVAL RATE
0.86 KG/HR
TREATMENT LENGTH
1:45 HR:MIN
DIALYSIS TEMP.
37.0 C
BP CUFF INTERVAL
15 MIN.
PRESS HERE TO CHANGE LEVEL IN DRIP CHAMBER
MORE INFO
UNDO ALL CHANGES
BACK TO CHOICES
16
18
20
30

FIG. 6



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/13969

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :B01D 61/32
US CL :210/143
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 210/143, 321.71, 646, 647, 929; 604/4-6; 248/917, 919-923; 345/173, 904, 905; 361/681, 682; 364/188, 395/140, 326

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,472,614 (ROSSI) 05 DECEMBER 1995 (see entire document).	1-7, 9 and 11-13
Y	US, A, 5,330,415 (STORTI ET AL) 19 JULY 1994 (see entire reference).	18-23, 27 and 29
Y	US, A, 5,247,434 (PETERSON ET AL) 21 SEPTEMBER 1993 (see entire document).	1-13, 15-29
Y	US, A, 5,187,641 (MUSKATELLO ET AL) 16 FEBRUARY 1993 (see entire document).	18-23, 27 and 29
Y	US, A, 5,108,063 (KOERBER ET AL) 28 APRIL 1982 (see entire document).	18-23, 27 and 29
Y	US, A, 5,056,059 (TIVIG ET AL) 08 OCTOBER 1991 (see entire document).	1-13, 15-17 and 24-28

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"B"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search
08 OCTOBER 1997

Date of mailing of the international search report
17 NOV 1997

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Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL [redacted]RCH REPORT

Inter[redacted]l application No.
PCT/US97/13969

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Group I, Claims 1-17 and 24-28.
Group II, Claims 18-23 and 29.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

INTERNAT L SEARCH REPORT

International application No.
PCT/US97/13969

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	GB, A, 2,110,564 (ELMAR MEDICAL SYSTEMS LIMITED) 22 JUNE 1983 (see entire reference).	18-23, 27 and 29

Form PCT/ISA/210 (continuation of second sheet)(July 1992)★

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European Patent Office
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(11) EP 0 952 540 A1

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Remarks:
This application was filed on 21 - 05 - 1999 as a divisional application to the application mentioned under INID code 62.

(54) Information entry validation system and method for a dialysis machine

(57) Information is entered and validated by the operator of a dialysis machine (30) by converting (230) the entered information into a first form using a first conversion relationship such as ASCII. The information in the first form is next converted (238) into a second form using a second conversion relationship, such as floating point numeric. Thereafter the information in the second form is converted (244) back to the first form using the first conversion relationship. The information in the first form which resulted from the third conversion (244) is displayed (246 and 248) for acceptance for rejection by the operator. Displaying the information resulting from sequential multiple conversions (230, 238, and 244) assures an opportunity for the operator to evaluate the entries for accuracy. Re-display of the previously entered information repeatedly presents the operator with an opportunity to recognize human-induced errors.

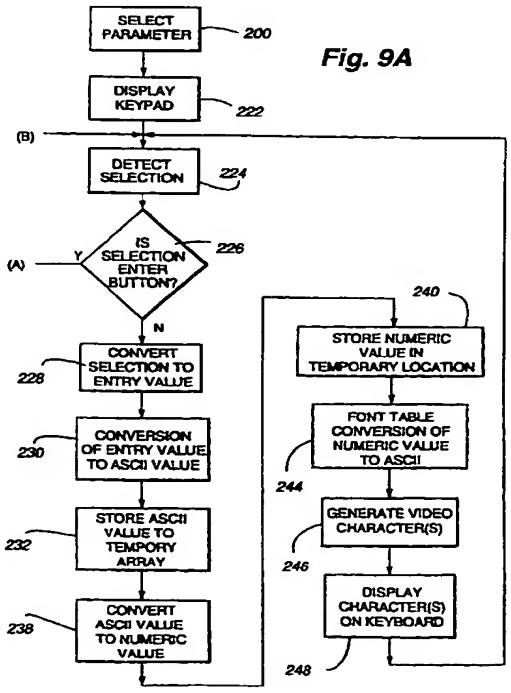

Fig. 9A

EP 0 952 540 A1

Description

[0001] The present invention relates to a new and improved dialysis machine and method of validating information entered by a machine operator to control the machine during dialysis treatment. More particularly, the present invention effectively confirms that the entered information is what the operator intended and that the machine validly accepted the information, all of which occurs more conveniently for the operator while maintaining safety according to commonly accepted safety standards.

Cross Reference To Related Inventions

[0002] This invention is related to the inventions described in U.S. patents for a Graphical Operator Machine Interface and Method for Information Entry and Selection in a Dialysis Machine, U.S. Patent No. 5,609,770, and for a Single Microcontroller Execution of Control and Safety System Functions in a Dialysis Machine, U.S. Patent No. 5,618,441, both of which were filed concurrently herewith. The disclosures of these patents are incorporated herein by this reference.

Background of the Invention

[0003] In general, a dialysis machine is used as a substitute for the natural kidney functions of a human body. As such, the dialysis machine cleanses the blood of the natural accumulation of bodily wastes and separates the wastes from the blood outside of or extracorporeally of the body. The separated wastes are discharged, and the cleansed blood is returned to the body.

[0004] The wastes are separated from the blood in a dialyzer. The dialyzer includes an internal housing which is separated by a porous medium into a blood side or compartment and a dialysate side or compartment. The blood removed from the patient flows through the blood side of the dialyzer. A prepared solution of dialysate is passed through the dialysate side of the dialyzer. The wastes from the blood pass through the medium by osmosis, ionic transfer or fluid transport into the dialysate and, depending upon the type of dialysis treatment, desirable components from the dialysate may pass in the opposite direction through the medium and into the blood. The transfer of the wastes into the dialysate cleanses the blood while allowing the desired components from the dialysate to enter the bloodstream.

[0005] As is apparent, the dialysis machine must be properly operated to perform effective dialysis in a safe and reliable manner. With the blood of the patient being removed and handled outside of the patient's body in an extracorporeal flow path, care must be taken that the treatment progresses safely and as intended according to the dialysis prescription for the patient. Since the patient's blood and the dialysate separated only by the dialyzer medium, it is apparent that numerous safety concerns must be satisfied on a continual and reliable basis.

[0006] Because of the potential for extremely serious consequences resulting from a failure or other unsafe condition, modern dialysis machines incorporate a large number of safety features as well as extensive control system features. The safety features include sensors located in the extracorporeal and dialysate flow paths to derive signals representative of the operating conditions or parameters which indicate the proper operation of the dialysis machine and/or the early development of a safety or risk condition. The control system features result in operational control over the pumps, dialysate heater, flow control valves and other devices associated with the extracorporeal and dialysate flow paths.

[0007] Because of the pre-eminent importance of the safety system, all known modern dialysis machines utilize microcontrollers or similar types of processor devices to execute the safety functions. Generally speaking, modern microcontrollers offer a greater possibility of more effective control over the safety features than other types of safety systems. Typically one microcontroller is used to execute the safety functions, and at least one and frequently two other microcontrollers execute the control system functions. Upon recognizing a safety or risk condition, the safety microcontroller takes control of the dialysis machine and places it in a safe state which prevents or greatly reduces the risk of injury to the patient.

[0008] In large measure, the use of separate microcontrollers for the safety and control systems is a result of the relatively stringent standards established by governmental, health and safety groups pertaining to dialysis machines. The multiple-microcontroller approach to achieving the basic safety and control system functions satisfies the regulatory standards by making the functionality of the safety system microcontroller independent of and separate from the functionality of the control system microcontroller.

[0009] The safety standards also apply to the entry of the information when setting up the machine to perform the dialysis treatment, as well as to the entry of information during the progress of the treatment. In general, the safety standards are concerned with promoting operator accuracy when entering information, and assuring that the entered information is not corrupted before it is used by the control system and safety system microcontrollers.

[0010] Since in some cases the machine can not protect against an operator-generated human error, many dialysis machines require the operator to enter information twice before the microcontrollers will accept the information. The theory behind th- double-entry requirement is that the operator is more likely to recognize an error if the operator is required to check, view or consider the entered information twice. Generally the first entry results in the information being recorded in

memory and then displayed to the operator. After the operator has again entered the same information, the microcontroller compares the first and second entries. If the two entries are the same, the first entry previously recorded in memory will be transferred to the control system and safety system microcontrollers for use during the treatment. Other typical information entry techniques used in dialysis machines display the second entry in a separate location from the display of the first entry. The operator must then mentally compare the two entered values, and if they are equal, accept the entered value. In this double-display technique, the dialysis machine does not make the comparison, but instead leaves the comparison to the operator.

[0011] An example of a prior art double-display information entry technique is provided in U.S. Patent No. 5,247,434 wherein an operator enters dialysis machine control information through the use of a touch screen key pad. Once the information has been entered (i.e., once the operator has pressed an ENTER button), the dialysis machine displays the newly entered information on the touch screen and prompts the operator to verify that the new information is accurate. The disclosed verification process is performed by requiring the operator to press a VERIFY button on the touch screen within a predetermined amount of time (e.g. five seconds). Thus, the disclosed double-display technique requires an operator to manually verify each information entry.

[0012] While the double-entry and double-display techniques have generally proved successful, it is somewhat tedious, repetitious and time-consuming for the operator. The typical machine setup procedure requires the entry of a significant number of different values, and the time associated with the double-entry detracts from the other activities required to ready the machine for treatment. Furthermore, the repetitiveness of the entries can lead to a type of monotony which may cause the operator to be less vigilant in visually comparing the two displayed values, or which results in a certain level of tension and tedium resulting from making the second entry, or which results in frustration when the operator encounters difficulty in correctly entering the information in sequential entries.

[0013] These and other considerations have contributed to the evolution of the present invention which is summarized below.

Summary of the Invention

[0014] One of the significant aspects of the present invention pertains to an information entry system and method which requires the operator to enter the value only a single time, but which achieves a standard of validation that satisfies existing safety standards relating to the entry of information in dialysis machines. Another aspect of the invention relates to alerting the operator if the information which has been entered has been corrupted by the machine. Another aspect of the invention relates to entering and validating information in a manner which will assure that both the control system and safety system microcontrollers validly receive the same information which the operator has entered and approved. A further aspect of the invention relates to an information entry validation technique in which the proper functionality of certain input/output (I/O) devices is confirmed as an adjunct of the information entry. Still another aspect of the invention relates to a convenient and user-friendly technique for entering and confirming information used by a dialysis machine.

[0015] In accordance with these and other aspects, the present invention pertains to a system and method for a dialysis machine in which entered control and safety information is validated. The machine includes an information entry device, for example a touch screen, and a display device, for example a cathode ray tube (CRT). A safety system of the machine receives information entered from the entry device. The entered information is first converted into a first form using a first conversion relationship. The information in the first form is next converted into a second form using a second conversion relationship. The second conversion relationship is different from the first conversion relationship. Thereafter the information in the second form is converted back to the first form using the first conversion relationship. The information in the first form which resulted from the third conversion is displayed on a display device for acceptance for rejection by the operator.

[0016] The multiple sequential conversions provide the operator with an opportunity to evaluate the internal functionality of the machine and to determine if the machine has corrupted the entered information. A malfunction will usually result in the information being displayed improperly or in an unusual form. Conversion of the information from one form into another form is likely to reveal that a corruption problem has occurred. Presentation of the displayed information only after and based on the sequential multiple conversions assures an opportunity for the operator to evaluate the entries for accuracy. With sequential entries, each new entry is subjected to the same series of conversions, but the collective value of the previous sequential entries is displayed. The re-display of the previously entered information repeatedly presents the information to the operator, but in a naturally-appearing manner which does not create the impression of duplicity, redundancy or multiple confirmation. As a result, the entered information is validated in a more time-conserving and reliable manner, while reducing the operator's workload without compromising the degree of validation.

[0017] Preferred aspects of the invention involve using an ASCII conversion relationship for the first conversion and a floating point numeric conversion relationship for the second conversion. The font table is employed to derive the information displayed to the operator. The use of the font table further confirms a state of proper functionality in the machine by notifying the operator if

the characters presented are improper or unusual. Improper or unusual characters would result from an error in the font table. Furthermore using the same font table to derive the characters for all of the displayed information has the additional benefit of confirming significant parts of the overall machine functionality, apart from the information entry.

[0018] Other preferred aspects of the invention involve storing the entered information in the second form into a third permanent memory location after the value has been previously stored in the second memory location. After the operator has accepted all of the values previously entered, the information in the second and third memory locations is compared. If the comparison reveals equal values in both locations, the information in the third memory location is displayed to the operator in a location which is different from that location where the same information was displayed while the operator entered the information. The information displayed from the third memory location is thereafter transferred to the control system of the dialysis machine for use during operation of the machine. An error detecting code is also calculated from the information in the second memory location and is stored in association with the information in the third memory location. The error detecting code is employed to validate the transfer of the information to the control system and/or the safety system.

[0019] Many other preferred aspects of the present invention, and a more complete appreciation of the present invention and its scope, may be understood from the accompanying drawings, which are briefly summarized below, from the following detailed description of a presently preferred embodiment of the invention, and from the appended claims.

Brief Description of the Drawings

[0020]

Fig. 1 is a perspective view of a dialysis machine which incorporates the present invention.

Fig. 2 is a generalized view illustrating a dialyzer, an extracorporeal flow path for blood from a patient through the dialyzer, and a hydraulics flow path for dialysate through the dialyzer, as are present during treatment of a patient with the dialysis machine shown in Fig. 1.

Fig. 3 is a block diagram of the control system and safety system of the dialysis machine shown in Figs. 1 and 2, illustrating the components which accomplish information entry validation according to the present invention.

Fig. 4 is an illustration of a screen display initially presented on a monitor of the dialysis machine shown in Figs. 1 and 3, prior to entry of information.

Fig. 5 is an illustration similar to that shown in Fig. 4, upon which a keypad is displayed for the entry of information.

Figs. 6, 7 and 8 are screen displays similar to those shown in Figs. 4 and 5, which illustrate other displays during the entry and validation of information according to the present invention.

Figs. 9A and 9B collectively form a single flow chart which illustrates steps involved in the entry and validation of information by a operator machine interface and safety microcontroller shown in Fig. 3.

Fig. 10 is another illustration of some of the steps in the flow chart shown in Fig. 9A and the relationship of those steps with a temporary memory array and a temporary numeric memory shown in Fig. 3.

Fig. 11 is an illustration of some of the steps in the flow chart shown in Fig. 9B and the relationship of those steps with a permanent memory shown in Fig. 3.

Detailed Description

[0021] An example of a dialysis machine with which the present invention may be advantageously employed is shown at 30 in Fig. 1. The dialysis machine 30 includes the devices generally shown in Fig. 2, and those devices establish an extracorporeal flow path and a hydraulics flow path. The extracorporeal flow path conducts blood from a patient 32 to a dialyzer 34, and then returns the blood from the dialyzer 34 to the patient 32. The hydraulics flow path conducts dialysate from a supply 36 to the dialyzer 34, and then returns the used dialysate to a waste drain 38.

[0022] The blood in the dialyzer 34 is confined to a blood chamber 40, and the dialysate in the dialyzer 34 is confined to a dialysate chamber 42. The blood chamber 40 and the dialysate chamber 42 are separated by a micro-porous or other type of dialysis medium 44. The waste products contained in the blood within the blood chamber 40 are transferred through the medium 44 by osmosis, ionic transfer or flow transfer to the dialysate in the dialysate chamber 42. Desirable components of the dialysate in the dialysate chamber 42 may also be transferred to the blood in the blood chamber 40 by the same mechanisms. In this manner, the waste products are removed from the patient's blood, and the cleansed blood is returned to the patient 32. The used dialysate flowing from the dialysate chamber 42 discharges the waste products into the drain 38 which may be a public sewer.

[0023] The elements of the extracorporeal flow path include at least one blood pump 46 which controls the flow of blood from the patient 32. An arterial line or tubing 48 extends through an arterial clamp 50 to a blood handling cartridge 52. The blood handling cartridge 52 is normally retained behind a door 54 of the machine 30 when used. The blood handling cartridge 52 is not shown in Fig. 1. The blood pump 46 also is located behind the door 54 and adjacent to the cartridge 52. The blood pump 46 is typically a peristaltic pump in dialysis machines.

[0024] Blood flows through the arterial line 48 and into an arterial chamber 56 of the cartridge 52. The blood pump 46 draws blood from the arterial chamber 56 through a pump tubing 58 which is squeezed or pinched by a rotating rotor 60 against a stationary raceway 62, in the typical manner of peristaltic pumps. The blood within the pump tubing 58 which is trapped rotationally in front of the point where the rotor 60 pinches the pump tubing is propelled through the pump tubing 58 and into a manifold 64 of the cartridge 52. A tubing 66 conducts the blood from the manifold 64 of the cartridge 52 into a blood inlet of the dialyzer 34.

[0025] The cleansed blood flowing from an outlet of the dialyzer 34 is transferred through a tubing 67 back to a venous chamber 68 of the cartridge 52. Blood from the venous chamber 68 is removed from the cartridge 52 through a venous tubing or line 70. Although not shown in Fig. 2, a venous blood pump similar to the arterial blood pump 46 may be located in the venous line to assist in forcing the bloods back into the patient 32 or to regulate the flow of blood through the extracorporeal flow path. If employed, the venous blood pump is positioned behind a second door 72 of the dialyzer machine 30 shown in Fig. 1.

[0026] After leaving the venous chamber 68 the blood flows through the venous line 70 to an air detector 74. The air detector 74 derives signals related to any air in the venous line 70. If an excessive or dangerous amount of air is present, a venous line clamp 76 will immediately close to terminate the flow of blood through the venous line 70 before the air reaches the patient 32.

[0027] Because the blood in the extracorporeal flow path is prone to clot, a blood anticoagulant such as heparin is injected into the extracorporeal flow path. The anticoagulant is slowly delivered from a syringe 78 as a result of a linear driver mechanism (not shown) moving a plunger 80 into the syringe 78. Anticoagulant from the syringe 78 is introduced into the arterial chamber 56 of the cartridge 52 through a tubing 82. The syringe 78 and the linear driver mechanism are typically referred to as an anticoagulant pump.

[0028] The elements of the hydraulics flow path include a number of different valves (some of which are not shown) and a dialysate pump 84 which draws dialysate from the supply 36. The supply 36 is typically a mixture of chemicals and water which the dialysis machine prepares as the dialysate is used, or a previously prepared quantity of dialysate which is delivered to the dialysis machine 30. The dialysate pump 84 draws the dialysate from the supply 36 and delivers it through a dialysate supply tubing or line 86 to an inlet of the dialysate chamber 42 of the dialyzer 34. The dialysate flows past the medium 44 where it absorbs the waste products from the blood in the blood chamber 40. Any beneficial components within the dialysate which are desired to be transferred to the blood pass through the medium 44 and into the blood in the blood chamber 40.

[0029] Prior to entering the dialyzer 34, the dialysate is heated in a heater 88 to the normal human body temperature. The temperature of the dialysate entering the dialyzer 34 should be at body temperature to avoid removing or transferring heat to or from the patient. Excessively warm dialysate will harm blood cells. Excessively cool dialysate will chill the patient. Temperature sensors (not shown) are located in the dialysate supply line 86 to monitor the temperature of the dialysate.

[0030] Conductivity sensors (not shown) are present in the dialysate supply line 86 to measure the conductivity of the dialysate. The desired level of ionic transfer between the blood and the dialysate is achieved by predetermined conductivity characteristics of the dialysate.

[0031] The used dialysate containing the waste products is removed from the dialysate chamber 42 through a dialysate waste tubing or line 90 by operation of a drain pump 94. The dialysate containing the waste products is delivered by the drain pump 94 to the waste drain 38. The waste drain 38 may be a separate container which accumulates the used dialysate and accumulated waste products, or it may simply be a public sewer.

[0032] As a safety precaution, bypass valves 96 and 98 are positioned at the inlet and the outlet of the dialysate chamber 42, respectively. The bypass valves 96 and 98 are connected by a bypass line 100. Normally the bypass valve 96 directs the inflow of dialysate into the dialysate chamber 42, and normally the bypass valve 98 directs the outflow of dialysate into the dialysate waste line 90. If a safety condition is detected, the bypass valves 96 and 98 are operated to their alternative states, thereby directing the flow of dialysate through the bypass line 100, and bypassing the flow of dialysate around the dialyzer 34.

[0033] The elements of the extracorporeal flow path, which have generally been described above, are shown and referenced generally at 110 in Fig. 3. The extracorporeal flow path elements 110 are controlled by an extracorporeal microcontroller 112 or other similar processing device, as shown in Fig. 3. The extracorporeal microcontroller 112 executes a program recorded in a memory 114 to control the extracorporeal flow path elements 110.

[0034] The elements of the hydraulics flow path, which have generally been described above, are also shown and referenced generally at 116 in Fig. 3. The hydraulics flow path elements 116 are controlled by a hydraulics microcontroller 118 or other similar processing device. The hydraulics microcontroller 118 executes a program recorded in memory 120 to control the hydraulics flow path elements 116.

[0035] An operator/machine interface (OMI) and safety microcontroller 122 is also connected to the extracorporeal flow path elements 110 and the hydraulic flow path elements 116. The OMI and safety microcontroller 122 monitors the operating conditions in the

extracorporeal and hydraulics flow paths, and upon detecting a potentially risky condition for the patient, assumes control over the extracorporeal and hydraulics flow path elements 110 and 116 to place them into a safe patient state. The safety microcontroller 122 executes a program recorded in its memory 124 to monitor the operating conditions of the dialyzer machine 30 and the patient 32 during dialysis treatment, to determine potentially hazardous conditions, and to place the dialyzer machine in a safe patient state upon the detection of a hazardous condition.

[0036] The three microcontrollers 112, 118 and 122 communicate with one another to exchange information and confirm proper functionality, among other things, by use of a bus or network 126. In general, the extracorporeal microcontroller 112 and the hydraulic microcontroller 118 are generally responsible for the control functions of the dialysis machine. The safety microcontroller 122 is responsible for the safety functions of the dialysis machine

[0037] Use of the three microcontrollers meets the safety standards for dialysis machines. In general, the safety standards emphasize redundancy to avoid the possibility that a single equipment failure will place the patient in a hazardous condition. If the failure of a control system microcontroller occurs, the safety system microcontroller is capable of placing the dialysis machine in the safe patient state. For example, should the hydraulics microcontroller 118 fail, the safety microcontroller 122 can assume control over the hydraulics flow path elements 114 to achieve the safe patient state. Similarly, should the extracorporeal microcontroller 112 fail, the safety microcontroller 118 will assume control over the extracorporeal flow path elements 110 to achieve a safe patient state. If the safety microcontroller 122 fails, the extracorporeal and hydraulics microcontrollers are capable of placing the dialysis machine in a safe patient state.

[0038] Although it is typical to use multiple microcontrollers in dialysis machines to meet the safety standards, a dialysis machine which meets safety standards while using only a single microcontroller for executing the control system and safety system functions is described in the above mentioned U.S. Patent No. 5,618,441 for a Single Microcontroller Execution of Control and Safety System Functions in a Dialysis Machine. The present invention may be utilized with either single or multiple microcontroller dialysis machines.

[0039] Because it is necessary to enter various types of safety and operational information to achieve a particular dialysis treatment or prescription for a patient, the safety standards also govern the entry of information into the dialysis machine. In general, those standards are concerned with confirming to the operator that the information entered into the machine is what the operator intends. It is also important that the operator know that the information entered is the information accurately stored in the memories 114, 120 and 124. The other general safety concern regarding information entry is that the safety microcontroller 122 and the control system microcontrollers 112 and 118 commence operations using the same entered information. If the safety and the control systems do not start with the same information, it will be extremely difficult or impossible to detect a difference in operation of the two systems, and such a difference could give rise to a safety situation.

[0040] The present invention achieves a more convenient and natural approach to entering and validating information into a dialysis machine, without compromising the safety standards and while simultaneously supplying better information to the operator concerning the safety and operating conditions of the dialysis machine.

[0041] The operator-machine interface (OMI) is the means by which information is entered into the dialysis machine and by which the entered information is validated back to the operator. The OMI functionality is incorporated with that of the safety microcontroller 122 shown in Fig. 3, or could be performed by its own microcontroller. By entering all information through the safety microcontroller 122, it is assured that the control system microcontrollers 112 and 118 will start with the same values or information which is initially recorded in the safety microcontroller 122.

[0042] The preferred means for entering and for displaying the entered information back to the operator is a conventional touch screen 130 attached to a front viewing surface of a conventional cathode ray tube (CRT) 132. The touch screen 130 and the CRT 132 are incorporated in a monitor 134 of the machine 30 shown in Fig. 1.

[0043] The touch screen 130 is a thin transparent sheet assembly which physically overlays a front viewing surface of the CRT 132. The overlaying relationship is generally illustrated in Fig. 3. With the touch screen 130 in position, the images displayed on the viewing surface of the CRT 132 define locations which the operator may select by applying finger pressure to the touch screen 130 at the location of the images. The touch screen 130 generates signals which describe the X-Y coordinates of the position where the finger pressure is applied. Those signals are supplied to a conventional touch screen converter 136 which converts the X-Y signals from the touch screen 130 into corresponding signals which are supplied to the safety microcontroller 122. The programmed functionallty of the safety microcontroller 122 correlates the signals from the touch screen converter 136 with the location of the images displayed on the viewing surface of the CRT 132. The correlation is possible because signals are supplied by the safety microcontroller 122 to a video driver 138 to control the position and details of the images displayed on the viewing screen of the CRT 132. By correlating the X-Y position signals from the touch screen converter 136 with the viewing images defined by the signals delivered to the video driver 138, the microcontroller

122 is able to recognize those selections made by the operator touching the touch screen 130. This functionality is typical and well known for touch screen input and output (I/O) devices.

[0044] To alert the operator in the case of a safety or other condition, an audio alarm 140 and a visual alarm 142 are used in the dialysis machine 30. The audio and visual alarms 140 and 142 are controlled by a driver 144. The driver 144 responds to control signals supplied by the safety microcontroller 122 to create a visual alarm or signal or an audio alarm or signal when necessary.

[0045] An example of a visual display created by the safety microcontroller 122 and the video driver 138 is shown in Fig. 4. The visual display is shown as it appears on the viewing screen of the CRT 132, and it will therefore be referred to as a display screen 150. The display screen 150 is divided into different areas which present information concerning the functions and status of the dialysis machine. A relatively large main window area 152 shows a number of setup parameters for controlling the dialysis machine during treatment, in this example. A title bar 154 indicates that setup parameters shown in the main window 152.

[0046] The eight setup parameters shown in the main window 152 are the patient identification number at 156, the type of dialysis treatment at 158, the time for the dialysis treatment at 160, the heparin infusion rate during the treatment at 162, the dialysate flow rate during treatment at 164, the profile for delivering sodium in the dialysate during the treatment at 166, the profile for delivering bicarbonate in the dialysate during the treatment at 168, and the target loss or volume of waste products to the removed from the patient's blood during the treatment at 170. Other types of setup parameters could be displayed. U.S. Patent No. 5,609,770 described above for a Graphical Operator Machine Interface and Method for Information Entry and Selection in a Dialysis Machine describes an advantageous technique of selecting parameters and programming the dialysis machine.

[0047] In addition to the main window 152, the right hand border (as shown) or some other selected area of the display screen 150 is occupied by images which allow the operator to select functional features of the display for purposes of entering information or monitoring the performance of the machine for the treatment. Touching a screen image 172 allows the operator to index among various displays and, for example, select the setup parameters, as is shown of at 172 and 154. Touching the touch screen above a last screen image 174 allows the operator to toggle between the present display screen 150 and the previously presented display screen. Touching a treatment setup image 176 allows the operator to select from a list a dialysis functions that are expected to occur in conjunction with each treatment. A quick OPS image 178 allows the operator to select from a list of easy access functions that are not necessarily expected in each treatment.

[0048] The on and off operation of the blood pump 46 (Fig. 2) is controlled by touching the blood pump icon or image 180. The blood pump is turned on and off with each touch. The rate of blood pump operation may be adjusted incrementally upward or incrementally downward by touching an up arrow image 182 or a down arrow image 184, respectively. Continual finger pressure on either of the arrow images 182 or 184 causes repeated incrementation. When operating, the blood pumping rate is displayed in the location where the word "off" appears in the blood pump image 180.

[0049] The bottom border or other designated area of the display screen 150 also includes a number of images or icons which represent control and monitoring conditions associated with the patient and the dialysis machine. The image at 186 which states "resume" is selected to resume treatment if the blood pump operation has been stopped.

[0050] The image at 188 which states "UF" accompanied by a downward pointing arrow is selected when it is desired to reduce the amount of ultrafiltration which may be occurring during a treatment. Ultrafiltration is a well-known aspect of some types of dialysis treatments which involves the direct introduction of an ultrafiltration solution into the blood. The ultrafiltrate may be introduced into the extracorporeal flow path prior to the blood reaching the dialyzer 34 (Fig. 2) or after the blood has passed through the dialyzer. Of course, if ultrafiltration is not used during the treatment, no functionality will be achieved by touching the ultrafiltration image 188.

[0051] The image displayed at 190 is an icon representative of the dialyzer 34 (Fig. 2). Touching the dialyzer image 190 results in bypassing the dialysate flow around the dialyzer. The image or icon of a heart at 192 allows the operator to obtain information concerning the patient's blood pressure, if a blood pressure monitoring functionality is a part of the dialysis machine and a blood pressure cuff is connected to the patient.

[0052] Organization of the display screen 150 in this manner allows a more convenient, time-conserving, reliable and safety-promoting approach to setting up the dialysis machine and operating the machine during the treatment, as is described more completely in the above referenced U.S. Patent No. 5,609,770 for a Graphical Operator Machine Interface and Method for Information Entry and Selection in a Dialysis Machine.

[0053] One of important safety-promoting aspects of the display screen 150 is its interaction with the operator and with the functionality of the OMI/safety microcontroller 122 (Fig. 3) in validating information, particularly numeric values, entered by the operator during the setup of the machine for dialysis treatments and during modification of the operating parameters of the machine while the dialysis treatment is progressing. The aspects of the information validation technique according to the present invention are represented in the flow chart shown in Figs. 9A and 9B, and are illustrated in the

screen displays shown in Figs. 4-8.

[0054] The steps of the technique shown in the flow chart of Figs. 9A and 9B are executed by the OMI/safety microcontroller 122 in conjunction with the memory 124 connected to the microcontroller 122. Each of the steps shown in the flow chart of Figs. 9A and 9B are separately identified by reference numbers for convenience of description.

[0055] In order to employ the information validation technique of the present invention, the operator must first select a parameter to be modified or established. The selection of the parameter is shown in Fig. 9A at step 200. The selection is also shown in Fig. 4 where the touch screen is touched in the area above the screen image 172. The screen image 172 is highlighted and the word "setup" appears. The fact that the setup parameters have been selected appears in the title bar 154. The setup parameters which are available to the established or modified are shown in the main window 152.

[0056] For example, assume the operator desires to establish or change the value of the target loss of waste volume to the removed from the patient, as is displayed at 170. The operator presses the touch screen in the area above the target loss image 170 to select the target loss setup parameter. The target loss image 170 is highlighted, as shown in Fig. 5, thereby indicating to the operator that the target loss parameter can now be established or modified.

[0057] If the parameter selected for modification or establishment is one which allows selection of discrete numeric values, a keypad 202 (Fig. 5) is displayed on the display screen 150. The signals which define the keypad display 202 are created by the microcontroller 122 and the video driver 138 (Fig. 3), and the CRT 132 (Fig. 3) creates the keypad 202. The keypad 202 is presented in place of some of the images which otherwise occupy the right hand and bottom border areas of the display screen 150, as can be seen by comparing Figs. 4 and 5.

[0058] The keypad 202 includes areas which define numeric buttons 204, a selected parameter display area 206 which presents a title corresponding to the parameter selected at 170, a decimal point button 208, an escape button 210, a clear button 212, and an enter button 214. In addition, an up arrow 216 and a down arrow 218 are located adjacent to the display area 206 to be used for incrementing the value of the parameter shown in the display area 206, either upwardly or downwardly.

[0059] The logical and sensible display of the keypad 202 provides the very important information that the safety microcontroller 122 and a font table 220 (Fig. 3) of the memory 124 are correct and operating properly. The font table 220 contains information from which the signals for creating the numbers in the keypad 202 are derived. If the numbers on the keypad 202 are not properly formed, or if the numbers are not located in the positions where the operator expects them to he located, a malfunction can be immediately detected. The operator will recognize the malfunction as making the dialysis machine unreliable. Thus, the use of the font table 220 to create the keypad 202 is an important aspect of information supplied to the operator concerning the validation and proper functionality of the dialysis machine. Assuming that the information presented in the keypad 202 is correct, the operator will continue with the information validation technique of the present invention and use of the dialysis machine.

[0060] The described functionality which presents the keypad 202 is shown at step 222 in Fig. 9A. After displaying the keypad at step 222, the program flow ceases until an entry or selection made by touching the screen is detected at 224. A determination is made at 226 whether the selection detected at step 224 was from the enter button 214 (Fig. 5) or from some other button from the keypad display 202. The purpose of the enter button 214 is to represent the final acceptance of all of the information or numeric values which have just been entered. Until the operator finally accepts the selected information by touching the enter button 214 (Fig. 5), the program flow will continue at the step 228.

[0061] The step 228 involves converting the X-Y signals from the touch screen 130 into an entry value obtained by touching the numeric buttons 204 (Fig. 5), by use of the touch screen converter 136 (Fig. 3) and the correlation of the signals from the converter 136 with the signals generated by the microcontroller 122 to display the numeric values in the keypad 202 (Fig. 3).

[0062] The entry value derived at step 228 is thereafter converted at step 230 into an ASCII value. Typically the entry value determined at step 228 is directly memory mapped to an ASCII value. ASCII values are employed for the purpose of displaying all of the numbers and characters.

[0063] Rather than immediately display the ASCII value derived from the step 230, the information entry validation technique of the present invention employs additional important steps to confirm the accuracy and acceptability of the entered value to the operator while simultaneously confirming the proper operation and acceptance of the value by the safety microcontroller. After the entered value is converted to the ASCII value at step 230, the ASCII value is stored at step 232 in a temporary array 234 (Fig. 3) of the memory 124. The temporary memory array 234 is a collection of memory locations or cells in which the ASCII value for each entry is separately stored. The individual locations or cells of the array 234 to which the ASCII values derived from each entry are separately stored are shown individually at 236a, 236b, 236c,... 236n in Fig. 10.

[0064] After the ASCII value has been stored in the temporary array at step 232, the microcontroller 122 (Fig. 3) immediately converts the stored ASCII value into a different representation of the same information or value represented by the ASCII value, such as a numeric value, preferably a floating point numeric value.

The conversion to the different form is shown at step 238 in Figs. 9A and 10. The numeric value derived at 238 is stored at 240 in a temporary numeric memory location 242 (Fig. 3) of the memory 124. The temporary numeric memory location 242 is a segment or location within the memory 124 which the microcontroller 122 designates for receiving the numeric value.

[0065] Using the numeric value stored in the temporary memory location at step 240, the numeric value is immediately converted back into an ASCII value at step 244. The font table 220 (Fig. 3) may be used in this conversion if the inherent functionality associated with the conversion does not immediately convert the floating point numeric value into an ASCII value. The ASCII value thus derived is thereafter applied to the video driver 138 (Fig. 3), and in response, the video characters corresponding to the ASCII value are generated, as shown at 246 in Fig. 9A. The CRT 132 (Fig. 3) displays the character to the operator as shown at 248 in Fig. 9A. The display of the value appears in the display area 206 of the keypad 202 as shown in Fig. 6. Fig. 6 illustrates the circumstance where the numeric "6" button 204 has been selected by finger pressure, resulting in the number "6" being presented in the display area 206 (Fig. 6). In the example shown in Fig. 6, the entered value of "6" is the first value of 3 values to be entered.

[0066] After the selected characters are displayed in the display area 206 (Fig. 6) of the keypad as shown at step 248 in Fig. 9A, the program flow reverts back to the step at 224 to detect another entry or selection of information. With each subsequent entry of information the steps beginning at 228 and ending at 248 are executed. However, each separate information selection is stored in a separate memory cell 236a, 236b, 236c ... 236n, shown in Fig. 10. In the example shown by comparing Figs. 6 and 7, the first ASCII entry (the numeric value "6") is stored in the cell 236a; the second ASCII entry (the decimal point) is stored in cell 236b; and the third ASCII entry (the numeric value "3") is stored in cell 236c. If the entered information included additional selected values, all of the additional entries would be stored to subsequent memory cells and the last or nth ASCII entry would be stored in the last cell 236n.

[0067] Each time a numeric value is derived at step 238, all of the values which have previously been recorded in the cells 236a, 236b, 236c, ... 236n are used in the ASCII-to-numeric conversion, as is shown in Fig. 10. In this manner, the value displayed at step 248 (Fig. 9A) constitutes a measure of the collective accuracy of each value previously and presently entered. Since the collective information of all of the previous values is used in the last ASCII to numeric conversion, rather than simply updating the information previously displayed with each new conversion, any mistake in the selected values is likely to be recognized by the operator.

[0068] Furthermore, the entry and conversion technique provides the operator with an effective indication of whether the stored information may have become corrupted. Should the operator receive the display of a value which the operator did not enter, or if a previously entered value suddenly changes with a subsequent entry, corruption of the entered information is suggested. A circumstance of a computational malfunction in the two conversions (ASCII to numeric, and numeric back to ASCII) might also be suggested. In either circumstance, the operator is alerted to a potential malfunction within the dialysis machine, and the operator should recognize that the machine should not the used for the dialysis treatment.

[0069] The use of the font table to display the values also provides a continuing indication of the functionality of the system. Preferably the font table is the only font table employed in the safety system for the display of information to the operator. By use of the single font table, the potential problems of corruptions of multiple font tables is avoided. Reference to a single font table for all displayed characters is more likely to reveal a malfunction within the system, since data displayed by use of the single font table will indicate corruption through the improper display of that data. The likelihood that the font table itself has become corrupted will be apparent if other information displayed to the operator is improper. These types visual cues provided through the display of information constitute a continuing integrity check of the functionality of the safety system microcontroller 122.

[0070] Further still, the display of the entered information also creates certain inherent protections against operator induced errors. The repetitive display of the information previously entered constitutes a requirement that the operator continually accept the previous values as well as the present values entered. Each subsequent step of entering additional values inherently causes the operator to re-evaluate the previous information presented on the display area 206 of the keypad 202 (Fig. 5). Consequently the entry process inherently creates a naturally-appearing requirement for reconsideration and re-validation of the previously entered information. However, this form of re-validation occurs inherently in conjunction with the natural process of entering each new value, not as an artificial and time-consuming requirement to specifically enter data twice or to look at data appearing in two different locations on the dialysis machine. Validation of the entered information appears transparent to the operator, but the integrity of the validation does not compromise safety or encourage inattentive or slack practices by the operator. Entered information is validated in a manner which appears natural and second-nature to the operator. The awkward, time-consuming and somewhat frustration-prone necessity to continually compare two different values displayed at different locations on a screen, or to enter values twice, is avoided.

[0071] After all of the information has been entered in the manner shown and described in conjunction with Fig. 9A, the resulting end value is displayed in the dis-

play area 206 of the keypad 202, as is shown by the example of the value "6.3" in Fig. 7. The value thus derived is stored in the temporary ASCII array 234 (Fig. 3) and in the temporary numeric memory 242. Even though the desired value may be displayed correctly, this value will not be accepted for use by either the safety microcontroller 122 or the extracorporeal or hydraulics microcontrollers 112 and 118 of control system.

[0072] To make an entered value available for use by the control and safety system of the dialysis machine, the operator must select the enter button 214 as shown in Fig. 7. Selection of the enter button 214 initiates the program flow shown in Fig. 9B to assure that the information which has been validated by the operator will be recorded in a permanent memory segment 250 (Fig. 3) of the safety system memory 124. Once the value is recorded in the permanent memory segment 250, the control system microcontrollers 122 and 118 gain access to the information by reading the values in the permanent memory from the network 126. Touching the enter button causes the temporary ASCII memory array 236a, 236b, 236c, etc. to become available for reuse during the same process with the next selected information.

[0073] Detection of the enter button at step 226 causes the microcontroller 122 to calculate a cyclic redundancy check (CRC) value based on the information contained in the temporary memory location 242. The calculation of the CRC occurs at step 252 as shown in Figs. 9B and 11. A CRC is a value derived from the bit structure of the particular value contained in the temporary memory location 242, and the CRC is used to detect errors that may occur from corruption of the value occurring after the CRC has been calculated. Errors of this nature may sometimes arise from failures of memory or due to corruption occurring when information is transferred to or obtained from memory within the computer system. The CRC may be calculated by using any number of well known CRC calculation algorithms.

[0074] After calculation of the CRC at 252, the calculated CRC is associated with the numeric value from which it was calculated, and the numeric value and its corresponding CRC are stored in the permanent memory location 250 (Fig. 3), as shown at the step 254. The values stored in the permanent memory location 250 are in a form acceptable for use and transfer between the safety system and the control system microcontrollers of the dialysis machine. However before the numeric and CRC values are made available for use by the management system, a further validation of the values recorded in the permanent memory 250 is performed.

[0075] The numeric value stored in the temporary numeric memory location 242 is compared at step 256 to the numeric value stored in the permanent memory location 250. If the comparison at 256 reveals that the values in the two memory locations 242 and 250 are different, an error has occurred and the value stored in the permanent memory 250 is not reliable or consistent with the value which has previously been validated and accepted by operator action as represented by the value located in the temporary memory 242. In this circumstance, all previously entered values in the temporary memory locations 234 and 242 and in the permanent memory 250 are erased at step 258 and the program flow reverts back to step 224 (Fig. 9A). Erasing the values causes the operator to commence again the information entry and validation procedure shown in Fig. 9A.

[0076] If the comparison performed at 256 reveals that the values in memory at 242 and 250 are equal, the keypad display 202 is erased from the display screen 150 by the step shown at 260 in Fig. 9B. The absence of the keypad 202 from the display screen is shown in Fig.8. Thereafter, the value in the permanent memory 250 is converted to an ASCII value, as shown at 262. Again, the font table 220 may be employed to make the conversion if it is not inherent in the program which establishes the numeric value.

[0077] The microcontroller 122 supplies the ASCII value derived from the conversion at step 262 to the video driver 138, as shown at step 264, and the signals from the video driver 138 are used by the CRT 132 to display the final value, as shown at step 266. The final value displayed at 266 is the same value which was accepted by the operator by touching the enter button 214 of the keypad 202. However, since the keypad 202 has been erased at step 260, the final value is displayed on the setup parameter button 170 (Fig. 8) which was initially selected at step 200 to initiate the information entry and validation technique of the present invention.

[0078] After acceptance of the value in the permanent memory as determined by the comparison at 256, the value in the permanent memory 250 is available to be transferred to and used by the management system extracorporeal and hydraulics microcontrollers 112 and 118, respectively. Transfer of the value to the microcontrollers 112 and 118 results in that value being stored in their memories 114 and 120, respectively, as is shown at step 268. The use of permanent memory 250 (Fig. 3) for storing the values used by the safety microcontroller 122 assures that those values will be available to the safety system after start-up following a power loss to the dialysis machine.

[0079] The information entry validation technique of the present invention achieves a number of significant improvements for the operators of dialysis machines. The information entered by the operator is inherently validated in a convenient and time-conserving manner, as a natural adjunct to the entry of information itself. The entire value displayed is re-presented to the operator with each subsequent entry. Each subsequent entry therefore confirms all of the previous entries and presents the result to the operator. Should the operator have failed to recognize an error occurring from a previ-

ous entry, each subsequent entry of information presents another opportunity for the operator to recognize a previous error. Furthermore, the final entered value must be accepted by the operator by selecting the enter button to re-affirm the final acceptance of the entered information. The removal of the keypad upon selection of the enter button and the resulting display of the final value in the parameter setup button requires the operator to again confirm the value. These procedures for presenting information to the operator for confirmation appear to the operator as natural sequential events, not the redundant and repetitious double-entry and double-display confirmation operations which are typical in the prior art. As a result, the operator is less likely to make mistakes arising from boredom, from inattention inherent in repeating redundant actions, or from tension and tedium caused by the typical double-entry requirements of prior art dialysis machines. Furthermore, these significant operator advantages are obtained without compromising safety, and while meeting the safety and governmental standards which apply to dialysis machines. Further still, the present invention allows the operator to enter information more rapidly while still achieving these significant conveniences.

[0080] The information entry validation technique of the present invention also offers significant improvements in the functional operations associated with the information entry and validation. The use of two separate conversions, such as ASCII to floating point numeric, serves as a double-check on the functionality of the machine. Furthermore the use of a single font table by which to achieve the conversions eliminates the possibility that errors could occur in one font table that were not present in another font table. The use of multiple memory locations to store values obtained from the two conversions, and to store the permanent value substantially reduces the possibility that an error in the memory might allow a corrupted value to be used by the dialysis machine. The comparison of the temporary and permanent values before the final value is accepted for use by the control and safety systems of the machine constitutes a further check on the validity of the accepted information. Many other significant improvements will be recognized after the present invention is fully comprehended and appreciated.

[0081] A presently preferred embodiment of the invention and many of its improvements have been described with a degree of particularity. This description is a preferred example for implementing the invention, and is not necessarily intended to limit the scope of the invention which is defined by the following claims.

Claims

1. A dialysis machine (30) having an information entry device (130) by which an operator enters control and safety information for treatment of a patient by the machine and a display device (132) by which an operator receives internal information generated by the dialysis machine (30) describing the operation and safety conditions of the machine, said dialysis machine (30) comprising:

   a safety system connected to the information entry device (130) and the display device (132), the safety system including:
   a memory within which a single font table (220) is recorded; and
   means for controlling the display device (132) to display both the information entered through the entry device (130) and the internal information generated by the dialysis machine (30) utilizing only the single font table (220).

2. The dialysis machine (30) of claim 1 wherein:

   the display device (132) creates displays of information from the operator in response to the application of display signals to the display device (132); and
   the safety system is operative to:

   receive entered information from the entry device (130);
   generate internal information describing the operative conditions of the machine (30);
   correlate all entered and internal information to be displayed to the font table (220);
   create display signals corresponding to the entered and internal information from the correlation to the font table (220); and
   apply the created display signals to the display device (132) to display the entered and internal information.

3. A method of displaying dialysis machine information which describes operational and safety conditions of the machine and treatment characteristics while simultaneously confirming proper internal operation of at least a part of the dialysis machine (30), said dialysis machine (30) having a memory, an information entry device (130) by which an operator enters control and safety information for treatment of a patient by the machine and a display device (132) by which the operator receives internal information generated by the machine describing the operational and safety conditions of the machine, said method comprising the steps of:

   recording a single font table (220) in the memory of the machine,
   displaying both the information entered through the entry device (130) and the internal information generated by the dialysis machine (30) using only the single font table (220).

4. The method of displaying dialysis machine information of claim 3 wherein the display device (132) creates displays of information from the operator in response to the application of display signals to the display device (132); further comprising:

receiving entered information from the entry device (130);
generating internal information describing the operative condition of the machine (30);
correlating all entered and internal information to be displayed to the font table (220);
creating display signals corresponding to the entered and internal information from the correlation of the font table (220); and
applying the created display signals to the display device (132) to display the entered and internal information.

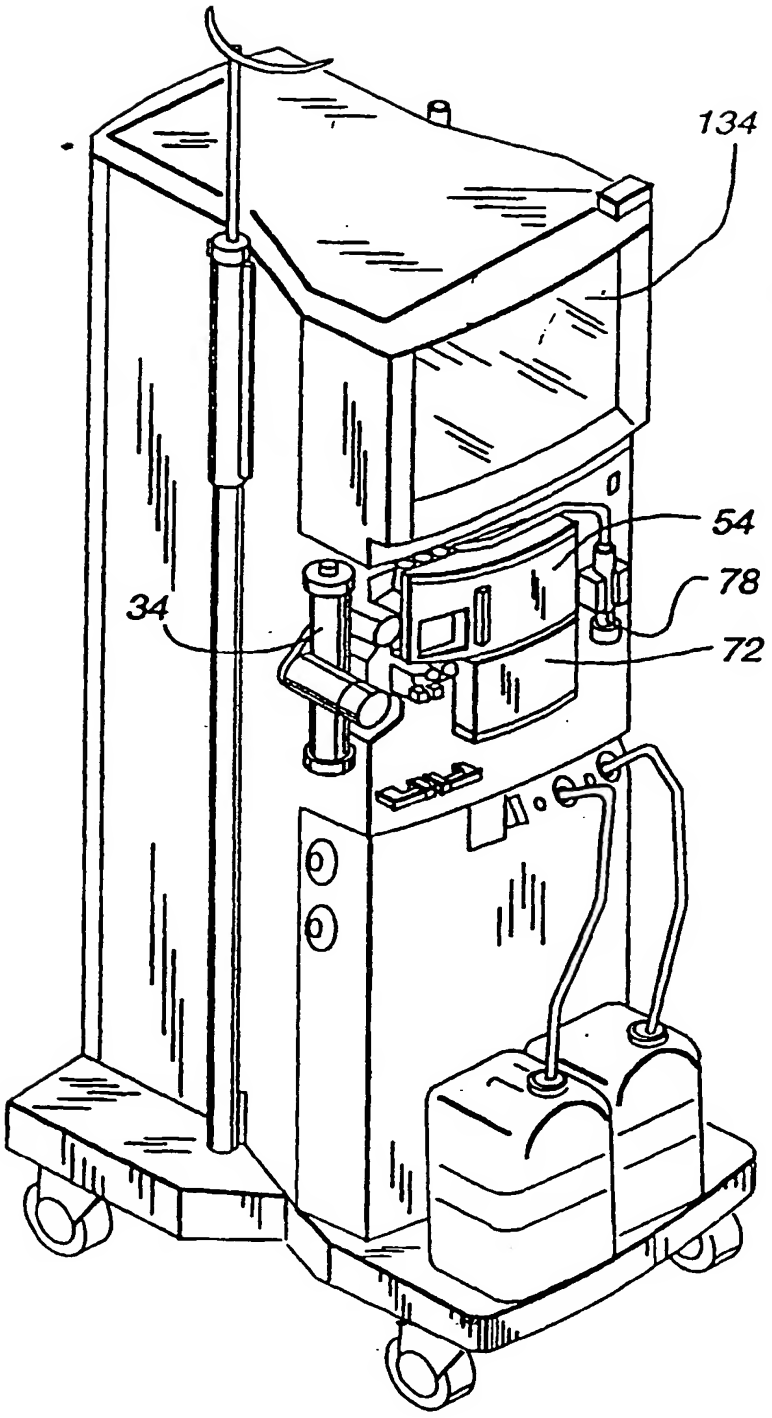

Fig. 1

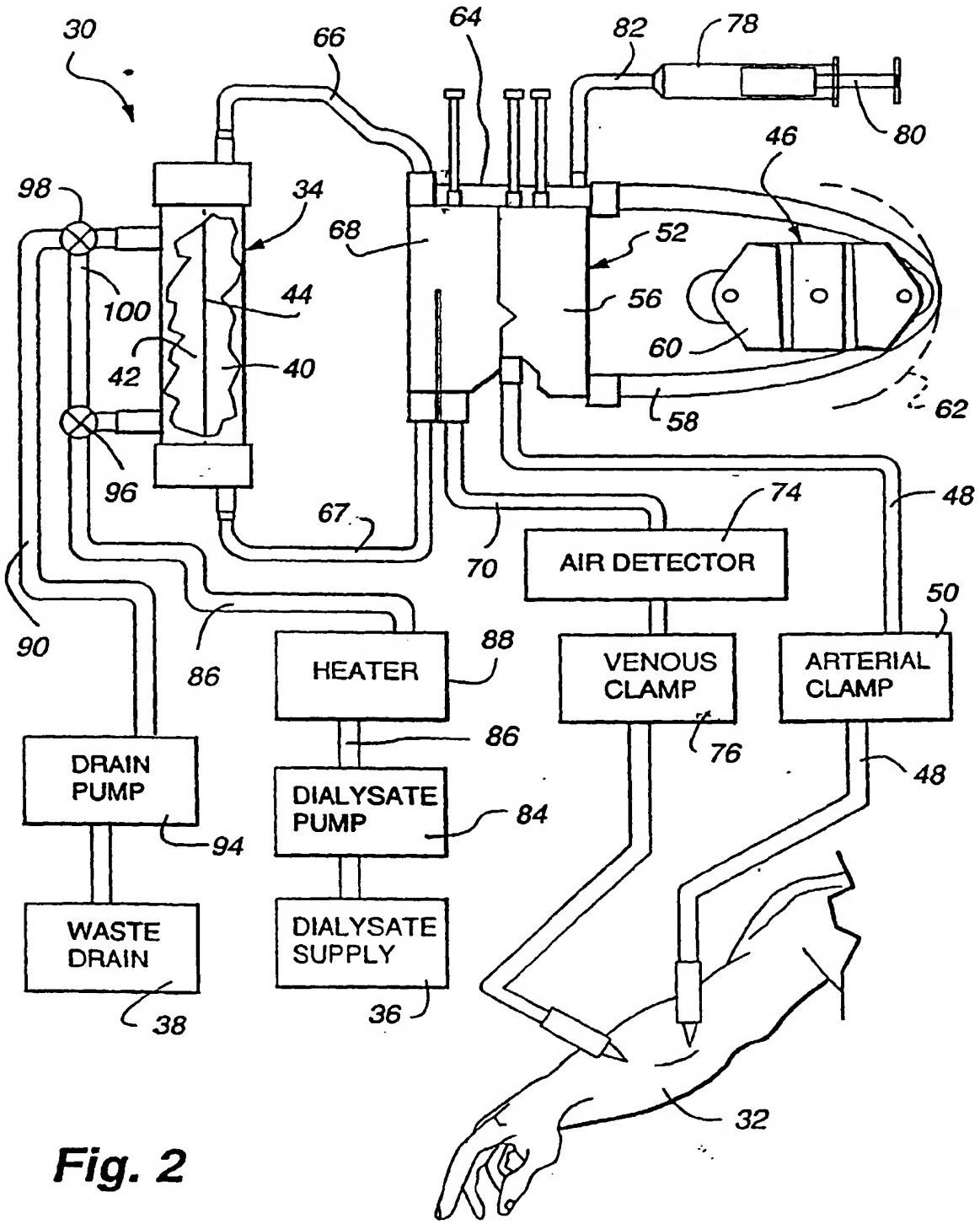

Fig. 2

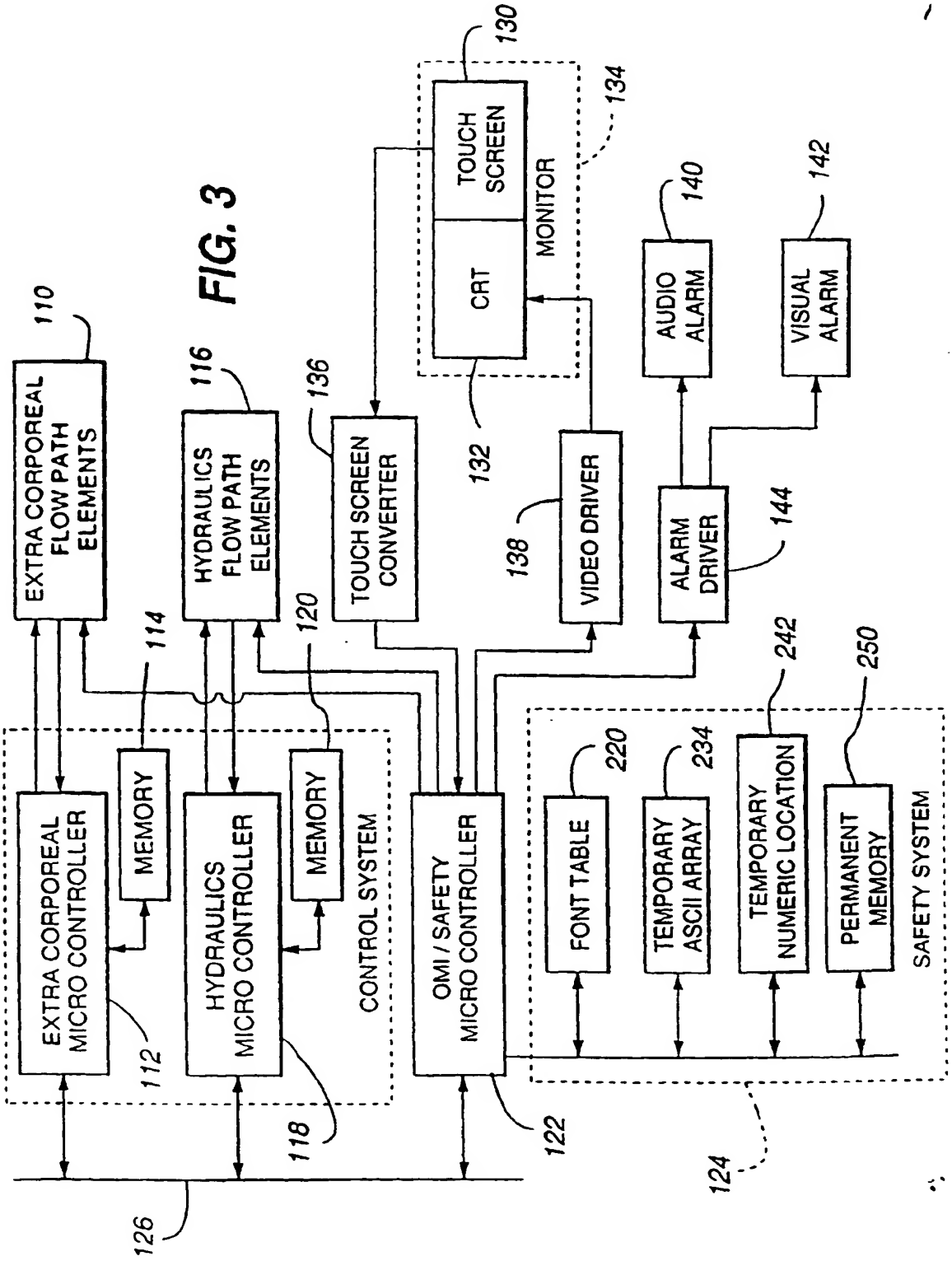

FIG. 3

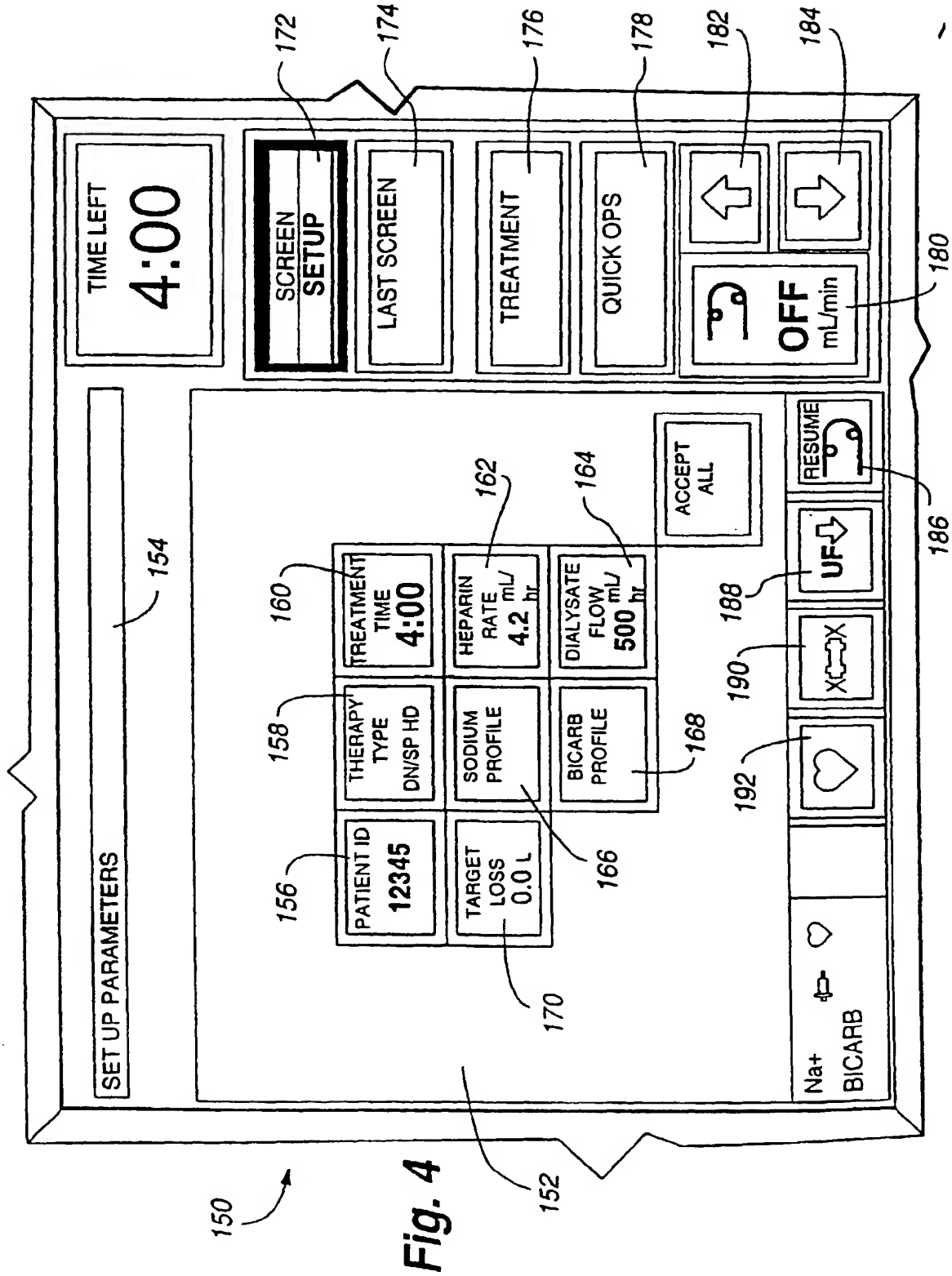

Fig. 4

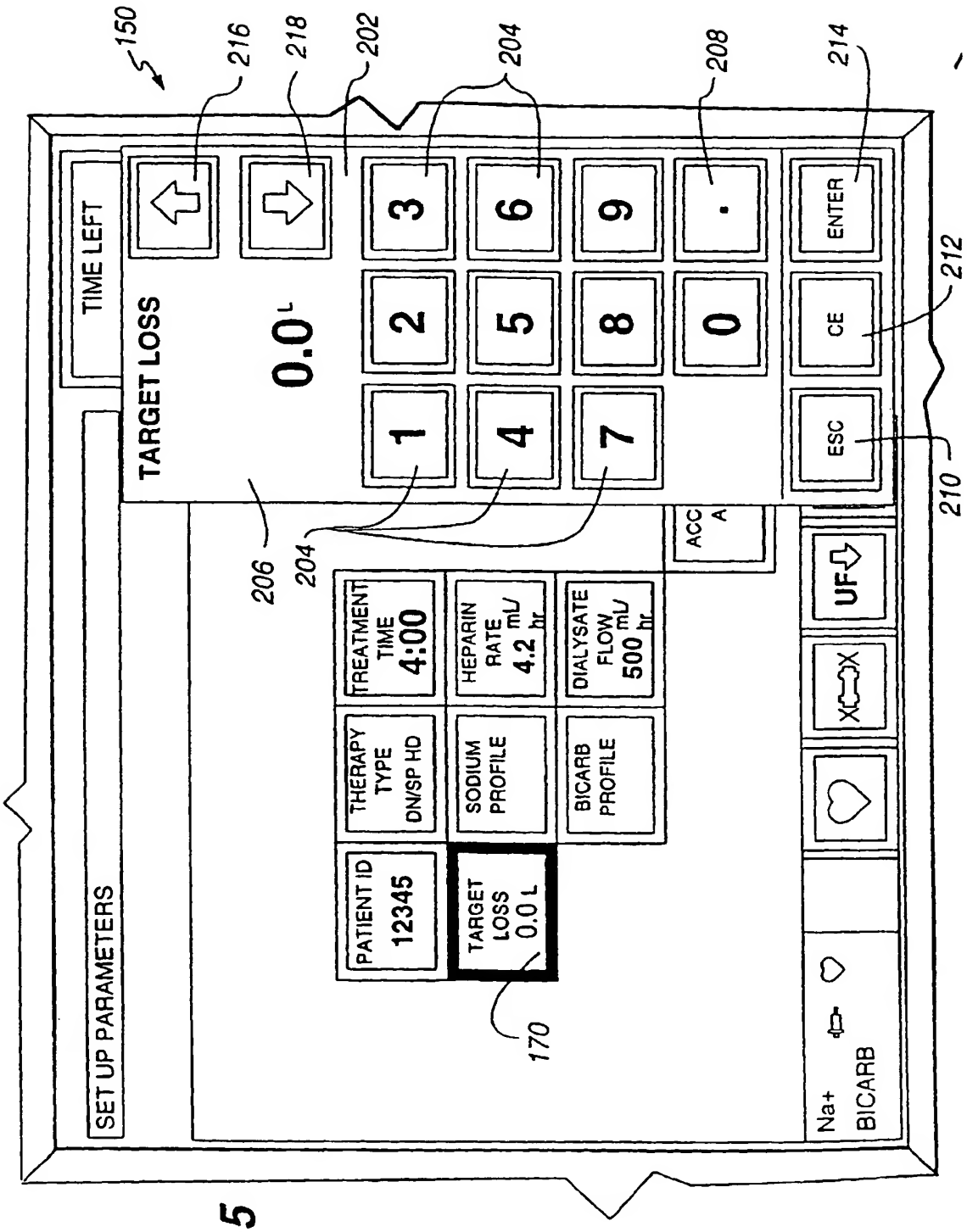

Fig. 5

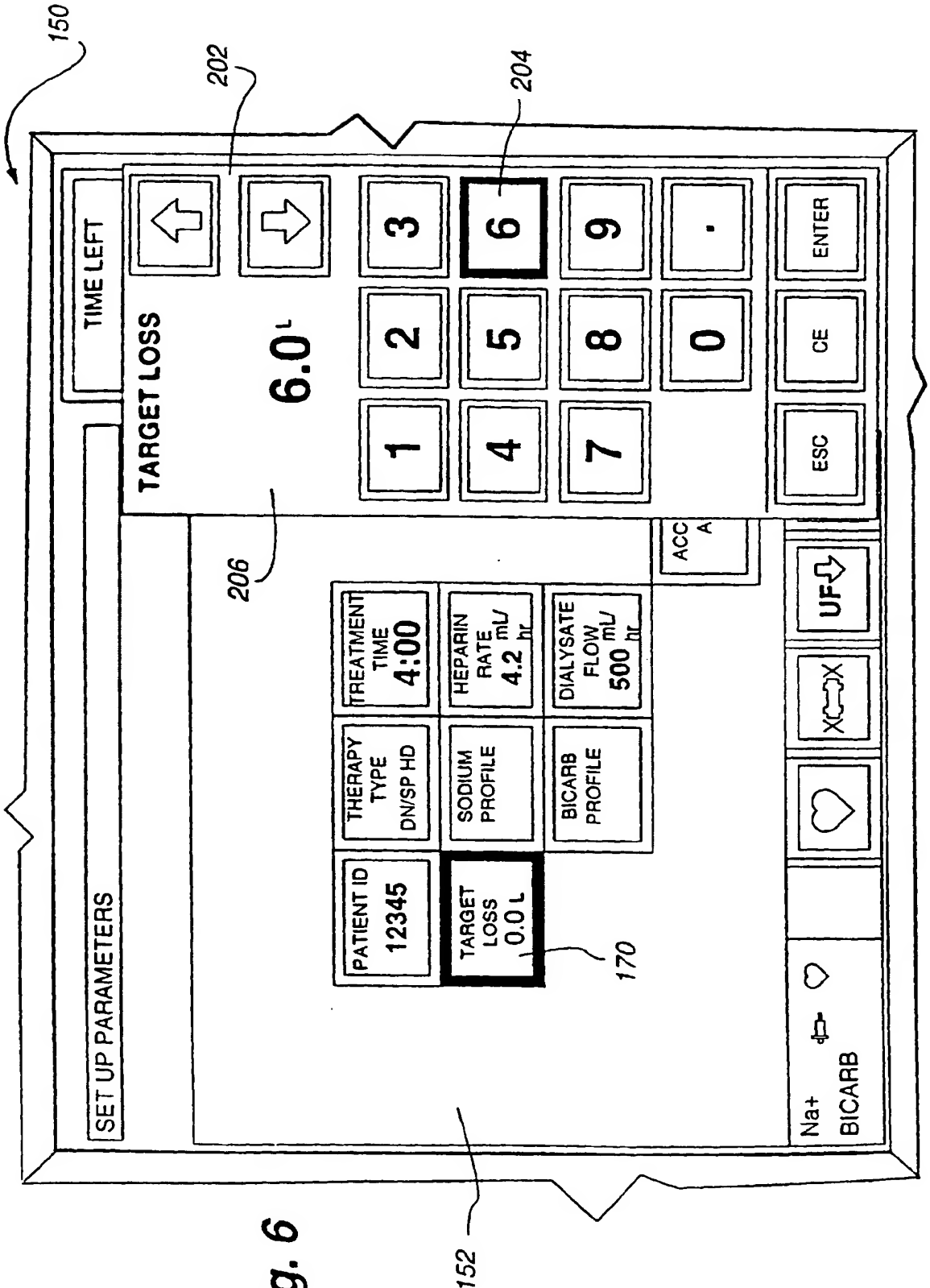

Fig. 6

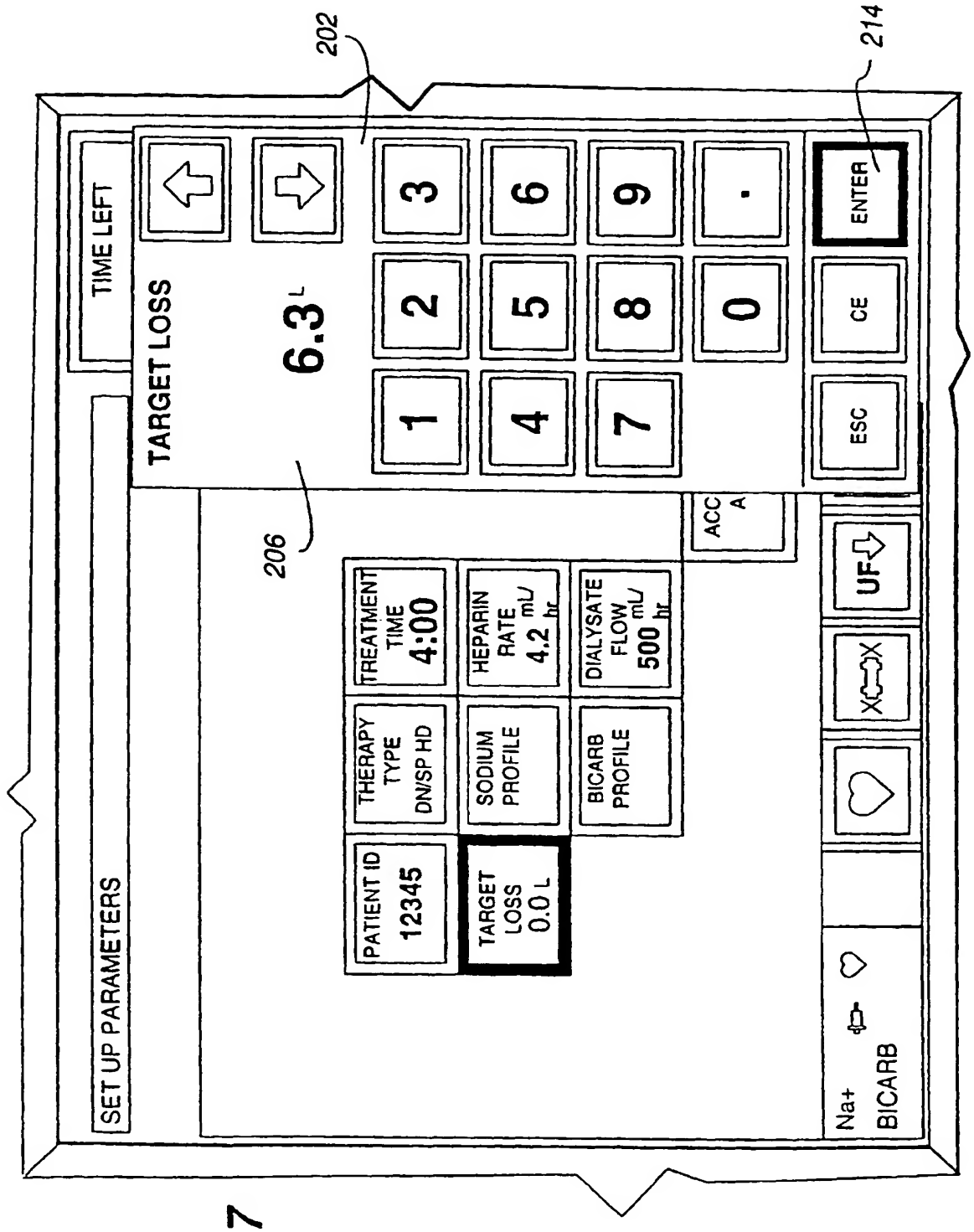

Fig. 7

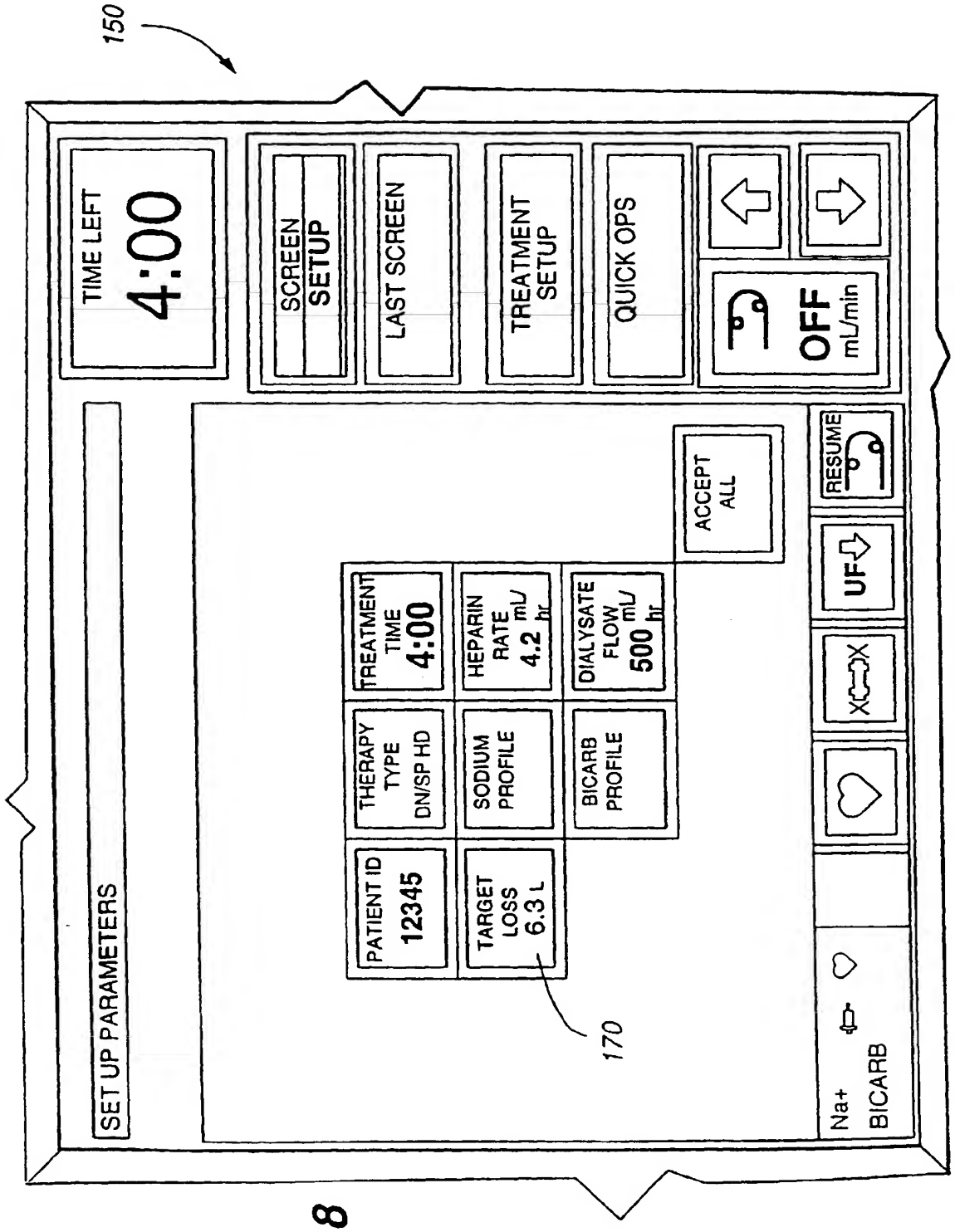

Fig. 8

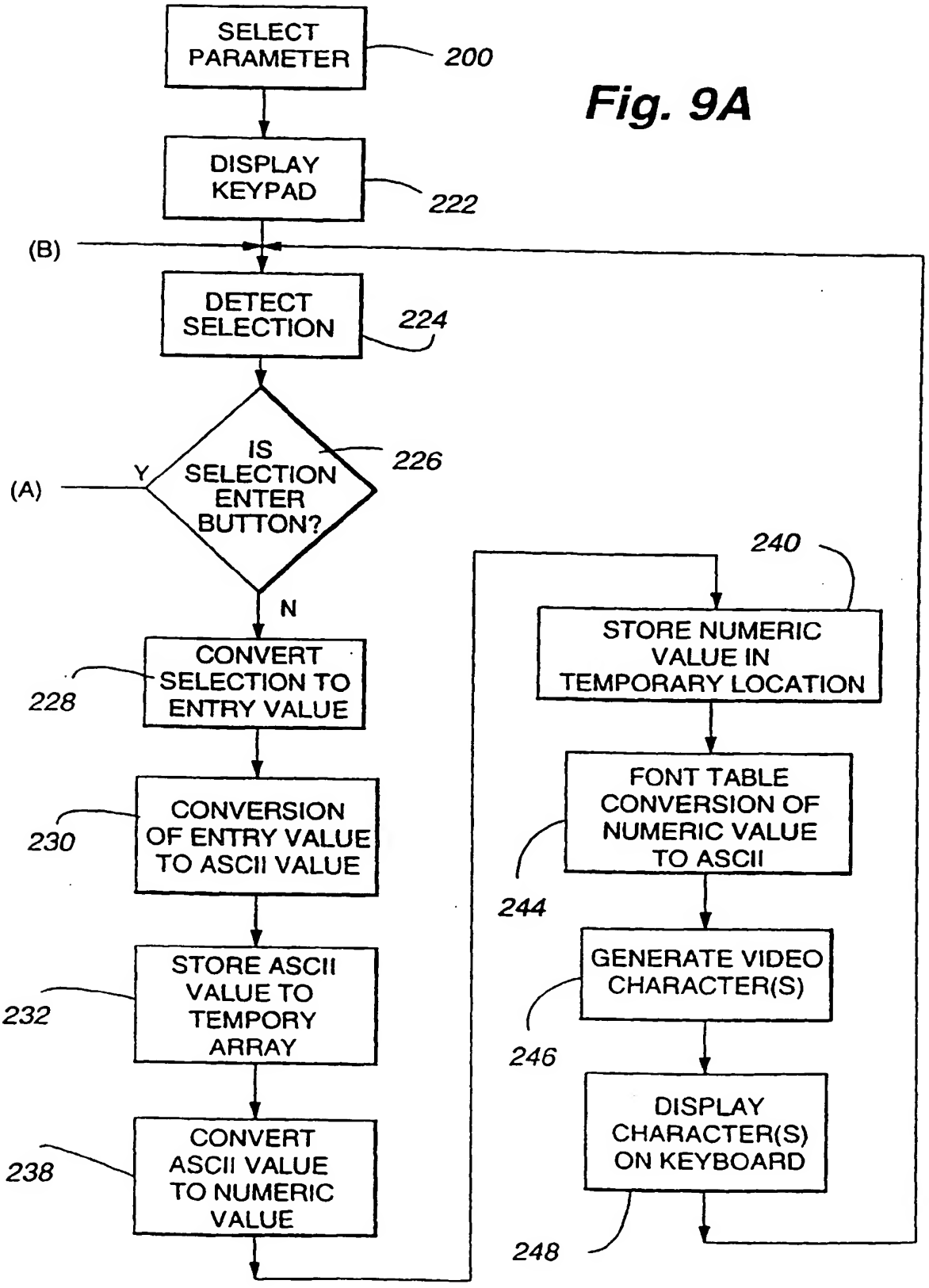

Fig. 9A

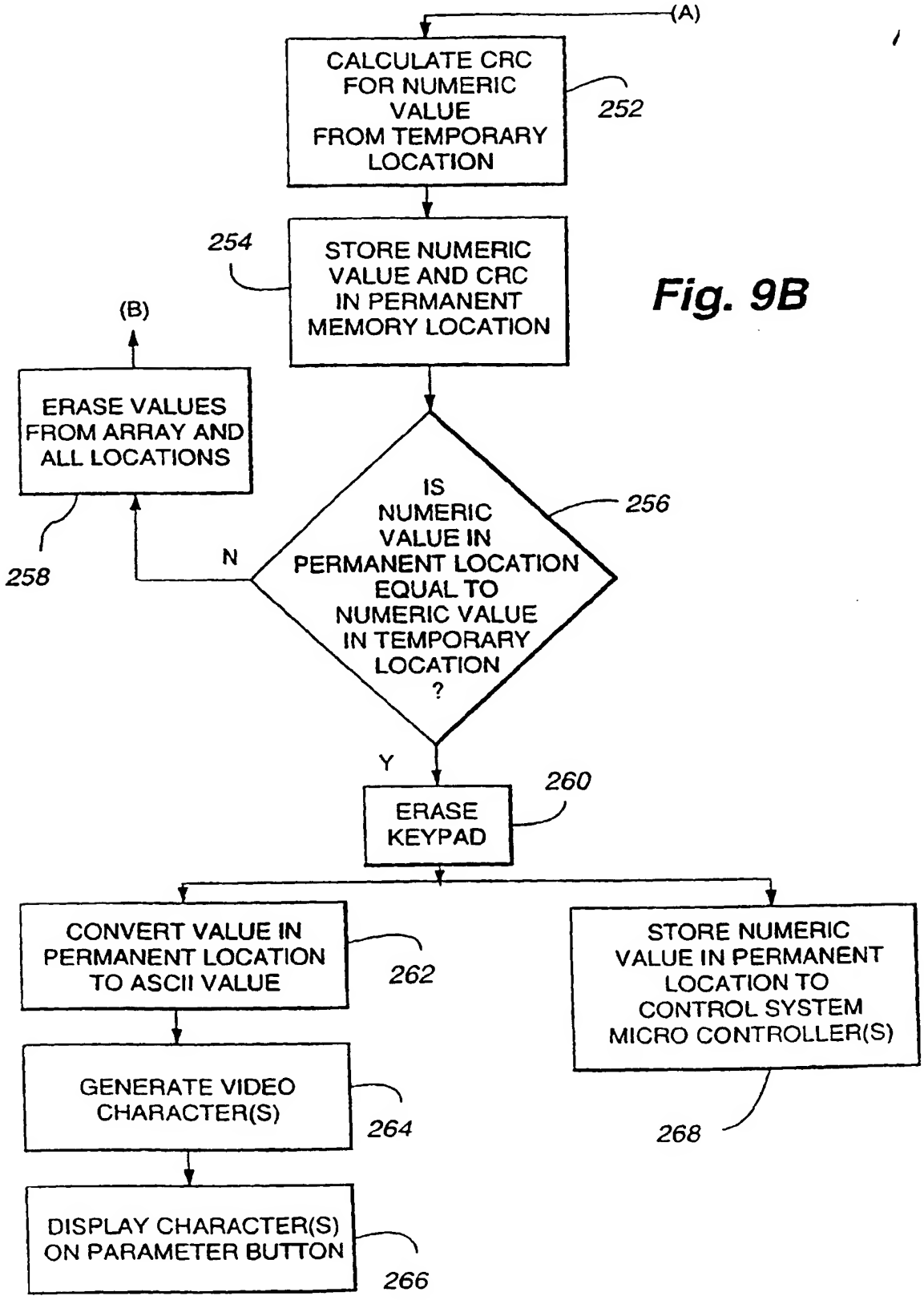

Fig. 9B

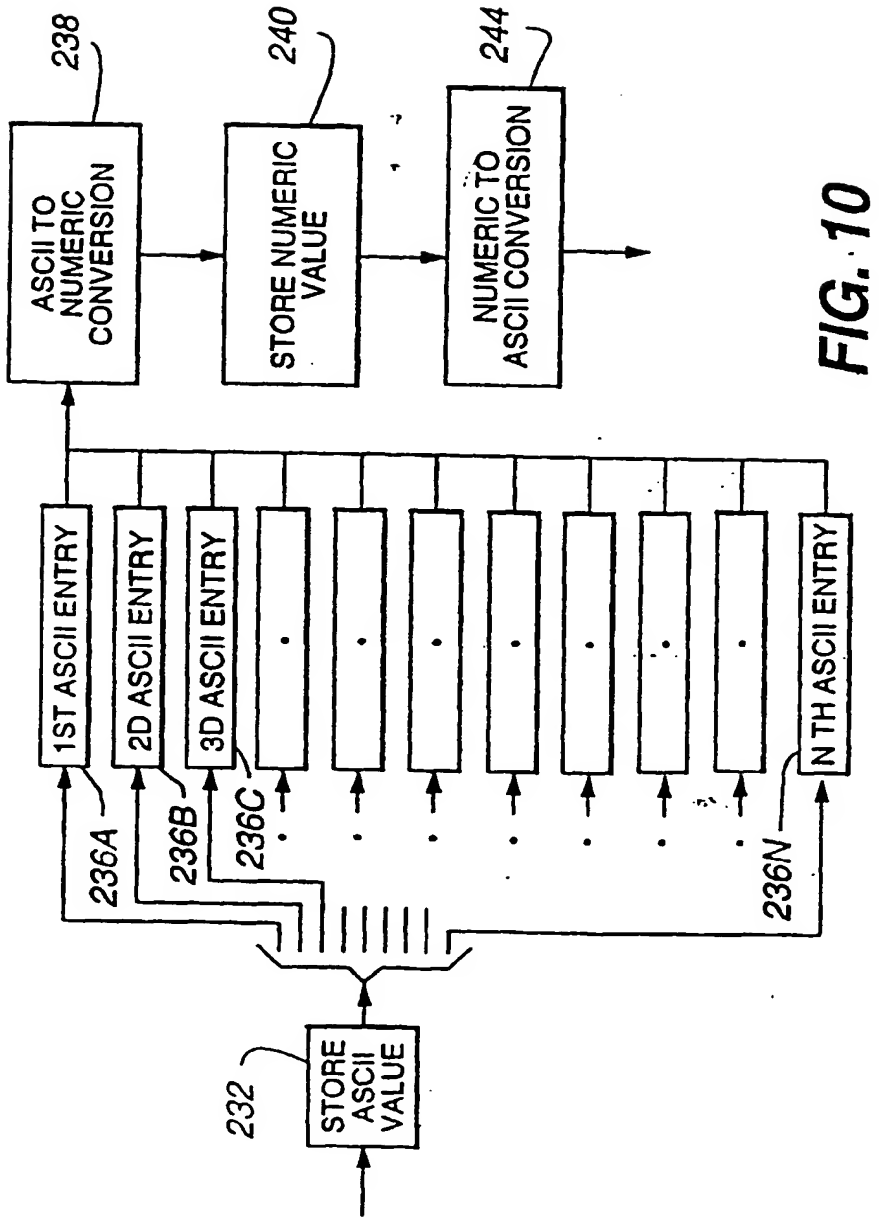

FIG. 10

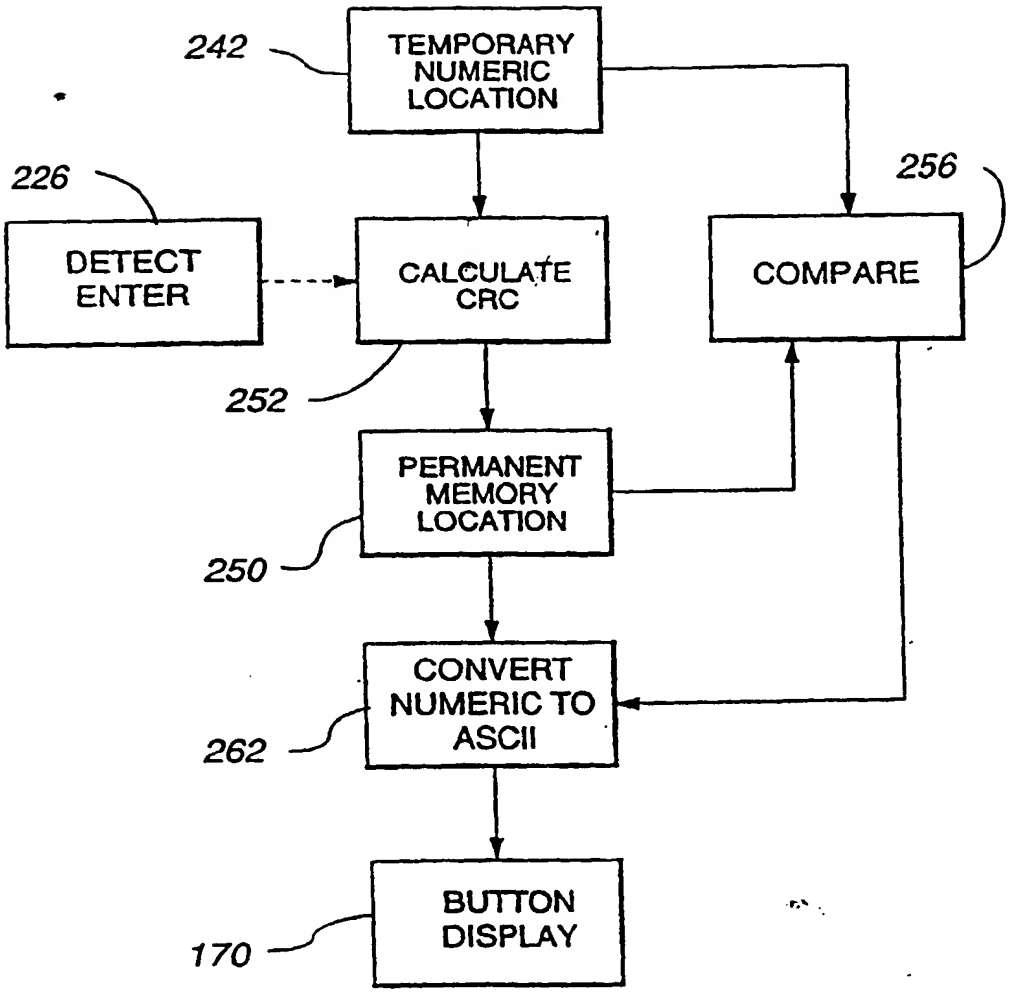

Fig. 11

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Place of search	Date of completion of the search	Examiner
MUNICH	20 August 1999	Barba, M

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